The Data used in this report is taken from the DAEN (Database of Adverse Events Notification) which is available at https://www.tga.gov.au/database-adverse-event-notifications-daen
This database is provided by the TGA (Therapeutic Goods Administration) who regulate the use

of pharmaceutical drugs in Australia. This database is being used in Australia to track Adverse Events (injuries including deaths) after Covid-19 Vaccination (as well as other medications). The latest data is 14 days delayed in this database.

An entry in this database does NOT prove a causal link to the injury or death reported.

However, it does not rule out a link either

The following slides are screenshots taken from this database to prove that the Adverse Events reported after Covid-19 vaccination (Cases) had a death reported also. We have taken a screenshot of the medDRA system organ class (i.e. the 'medicine summary' of injuries) as well as a screenshot of the 'List of Reports' which gives a breakdown of injuries on an individual basis. Both share a common field called 'medDRA reaction Terms.' In many cases (86% of all cases) this has allowed us to identify a death reported down to an individual case including age.

E.G. – Please refer to page 3 (Case Number 520837 – Male 92). In this instance there was 1 case reported for Loss of Consciousness under 'Nervous System Disorders' - Number of cases reported = 1 and Number of cases where death was a reported outcome = 1. We can conclude from this that the only individual entry for 'Loss of Consciousness' also resulted in a death being reported as this was the only case of this type reported on this day. We cross reference this case with the individual entry (List of Reports) and show the individual that this case and death was reported for.

Case No 515141 – Female – age 46

Extracted from DAEN between 01/04/22 to 30/6/22

■ 5 medicines selected between 21/01/2020 - 21/12/2020.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| | |
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

■ More information on the search results

| More information on | the search results | | | |
|--|--|---------------------|--|--|
| Medicine summary | <u>List of reports</u> | | | |
| Medicine summary | / | | | |
| The medicine summary adverse events. | groups reported adverse ev | ents together. Pati | ents may have re | ported multiple |
| Further information abou | ut the medicine summary | | | |
| Information on printing | search results | | | |
| Sort by: | | | | rsion of this |
| Number of cases - high | est first | | report | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 0 | 1 |

| Case | Report entry date | Age (Yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|--------|----------------------|--------------|--------|--|---|
| 515141 | 21/12/2020 | 46 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected Revestive (teduglutide) - Suspected Suspected | Abdominal discomfort Abdominal discomfort Abdominal distension Abdominal pain Adverse event following immunisation Arthritis Arthritis bacterial Bacteraemia Drug ineffective Dyspnoea exertional Endocarditis Fatigue Fluid retention Gastrointestinal stoma output abnormal Gastrointestinal stoma output decreased Headache Hepatomegaly Hunger Hypervolaemia Hypotension Inappropriate schedule of product administration Incorrect dose administered Intestinal ischaemia Joint swelling Lethargy Liver function test abnormal Lower respiratory tract infection Malaise Myalgia Nausea Peripheral swelling Pneumonia Rash Renal failure Sepsis Splenomegaly Therapeutic product effect decreased Thirst Tooth infection Urine output decreased Thirst Tooth infection Urine output decreased Vorniting Weight increased |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single $\underline{\text{suspected}}$ medicine: $\boldsymbol{1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Loss of consciousness | 1 | 1 | 1 |

Case No 520837 - Male - age 92

Extracted from DAEN 01/04/2022

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 520837 | 01/03/2021 | 92 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation Loss of consciousness |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------------|---|-----------------|--|--|
| Metabolism and nutrition disorders | Decreased appetite | 2 | 2 | 2 |

Case No 521153 – Female – age 98

Extracted from DAEN 01/04/2022

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 521153 | 03/03/2021 | 98 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Decreased appetite |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single $\underline{\text{suspected}}$ medicine: 3

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|----------------------------|--|-----------------|--|--|
| Gastrointestinal disorders | Vomiting | 3 | 3 | 1 |

Case No 521302 – Female – age undisclosed Extracted from DAEN 01/04/22

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 521302 | 04/03/2021 | - | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Decreased appetite Depressed level of consciousness Dysphagia Vomiting |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

<u>Medicine summary</u>

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

Case No 521311 - Male - age 76 Extracted from DAEN 01/04/22

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 521311 | 04/03/2021 | 76 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cardiac arrest Unresponsive to stimuli |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|---|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 2 | 2 | 2 |

Case No 521302 - Male - age 67 Extracted from DAEN 01/04/22

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 521667 | 05/03/2021 | 67 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|-----------------------------|--|-----------------|--|--|
| Infections and infestations | Sepsis | 1 | 1 | 1 |

Verifiable death

81 year old female

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 521683 | 05/03/2021 | 81 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | AspirationSepsisVomiting |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

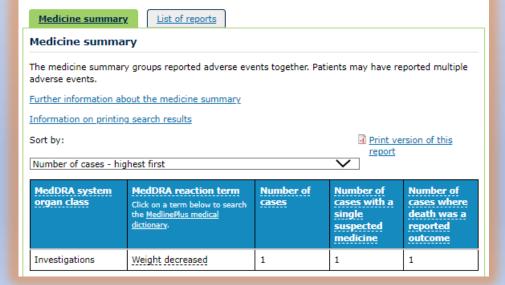
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



Verifiable death - Female – aged undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 521644 | 05/03/2021 | - | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Dysphagia Injection site reaction Somnolence Weight decreased |

We know this case had a death reported due to the other reactions having a death reported also (can filter using BETA DAEN)

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

Nervous system

disorders

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

Unresponsive to stimuli

■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report Number of cases - highest first $\overline{}$ MedDRA MedDRA reaction term Number of **Number of** Number of system organ cases with a cases where cases Click on a term below to search class the MedlinePlus medical single death was a suspected reported medicine outcome

Verifiable death

95 year old male

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 521789 | 06/03/2021 | 95 | М | Tradename not specified (trimethoprim) - Suspected COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Unresponsive to stimuli |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Dyspnoea | 1 | 1 | 1 |

Verifiable death – Male – Age 90

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 521743 | 06/03/2021 | 90 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Dyspnoea Vomiting |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Dyspnoea | 3 | 3 | 1 |

Verifiable death – Male – Age 92

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 522108 | 09/03/2021 | 92 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | • Dyspnoea |

■ <u>5 medicines selected</u> between 08/03/2021 - 14/03/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Ischaemic stroke | 1 | 1 | 1 |

Verifiable death

92 year old female

repere

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 522391 | 11/03/2021 | 92 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Ischaemic strokeMydriasis |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

Metabolism and

nutrition disorders

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

Diabetic ketoacidosis

More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report Number of cases - highest first $\overline{}$ MedDRA system MedDRA reaction term Number of **Number of** Number of organ class cases with a cases where Click on a term below to search the MedlinePlus medical death was a dictionary. suspected reported medicine outcome

Verifiable death

95 year old female

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 522414 | 11/03/2021 | 95 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Diabetic ketoacidosis Urosepsis |

Selected medicines

| Trade name | Active ingredients | |
|------------------------------|---------------------------------------|--|
| COMIRNATY COVID-19 vaccine | tozinameran | |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) | |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) | |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) | |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) | |

■ 1 MedDRA Reaction Terms selected.

Search results

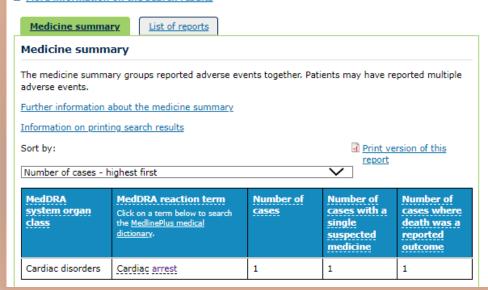
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



Verifiable death

83 year old male

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 522710 | 12/03/2021 | 83 | М | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Cardiac arrest |

Selected medicines

| Trade name | Active ingredients | | |
|------------------------------|---------------------------------------|--|--|
| COMIRNATY COVID-19 vaccine | tozinameran | | |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) | | |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) | | |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) | | |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) | | |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Respiratory failure | 1 | 1 | 1 |

Verifiable death – Male – Age 93

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 522731 | 12/03/2021 | 93 | М | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | Pneumonia Respiratory failure |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single <u>suspected</u> medicine: 1

Number of cases where <u>death</u> was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report $\overline{}$ Number of cases - highest first MedDRA **Number of Number of** MedDRA reaction term Number of cases with a system organ Click on a term below to search cases cases where class the MedlinePlus medical single death was a suspected reported medicine outcome Vascular disorders | Circulatory collapse

Verifiable death

83 year old female

| <u>Case</u> number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|-----------------------|----------------------|--------------|--------|--|--|
| 523503 | 16/03/2021 | 83 | F | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | Circulatory collapse |

Selected medicines

| Trade name | Active ingredients | |
|------------------------------|---------------------------------------|--|
| COMIRNATY COVID-19 vaccine | tozinameran | |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) | |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) | |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) | |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) | |

■ 1 MedDRA Reaction Terms selected.

Search results

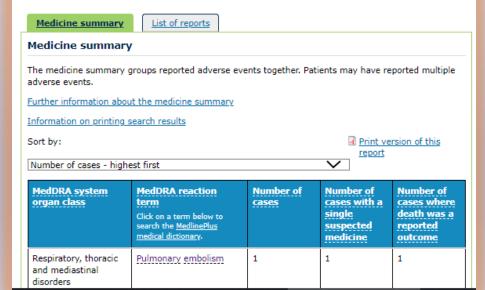
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results



Verifiable death

87 year old female

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 523387 | 16/03/2021 | 87 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected Tradename not specified (allopurinol) - Not suspected Tradename not specified (ferrous sulfate) - Not suspected Thyroxine (levothyroxine sodium) - Not suspected | • Pulmonary embolism |

Selected medicines

| Trade name | Active ingredients | |
|------------------------------|---------------------------------------|--|
| COMIRNATY COVID-19 vaccine | tozinameran | |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) | |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) | |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) | |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) | |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | General physical health deterioration | 1 | 1 | 1 |

Verifiable death

77 year old male

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 524083 | 18/03/2021 | 77 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | General physical health deterioration |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

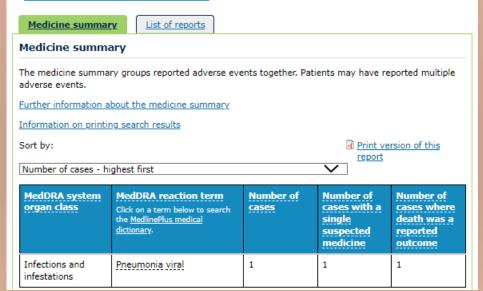
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

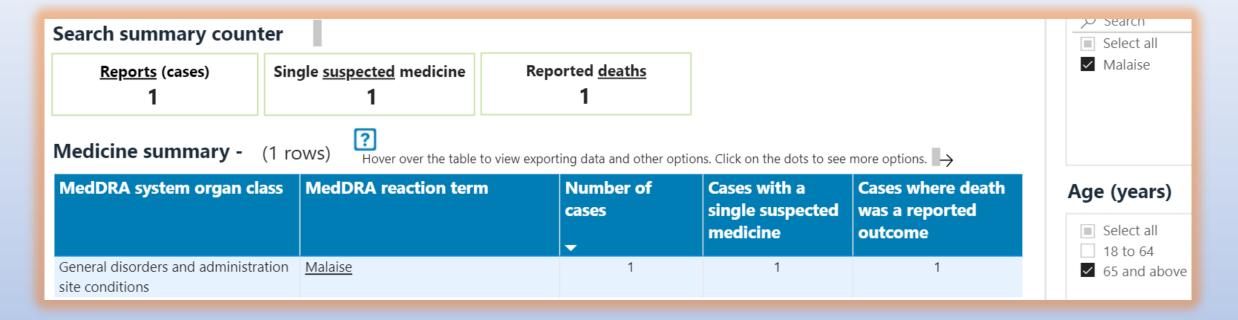


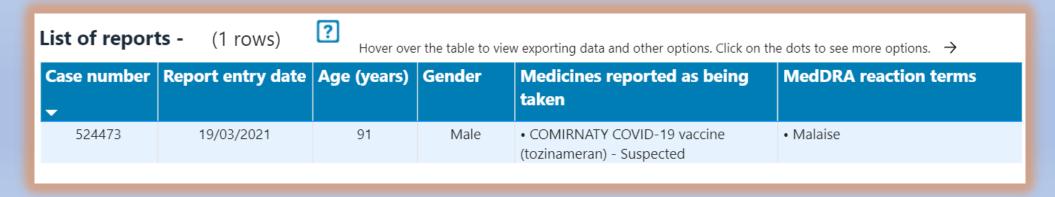
Verifiable death

96 year old male

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 524247 | 19/03/2021 | 96 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Pneumonia viral |

Verifiable death - Male = Age 91





Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| | MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|-----|---------------------------------|---|-----------------|--|--|
| - 1 | Nervous system disorders | Depressed level of consciousness | 1 | 1 | 1 |

Verifiable death

77 year old male

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 526002 | 24/03/2021 | 77 | M | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Depressed level of consciousness Pyrexia Rash |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Sort by: Print version of this report Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the <u>MedlinePlus medical</u> <u>dictionary</u> . | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Gastrointestinal disorders | Gastrointestinal haemorrhage | 1 | 1 | 1 |

Verifiable death

83 year old female

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 525796 | 24/03/2021 | 83 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Gastrointestinal haemorrhageRash |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

Nervous system disorders

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

Cerebral haemorrhage

More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report Number of cases - highest first $\overline{}$ MedDRA Number of **Number of** Number of MedDRA reaction term system organ Click on a term below to search the MedlinePlus medical dictionary. cases with a cases where class single death was a

reported

outcome

suspected medicine

Verifiable death

86 year old male

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 527413 | 26/03/2021 | 86 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cerebral haemorrhage Cerebrovascular accident |

■ <u>5 medicines selected</u> between 26/03/2021 - 26/03/2021.

Selected medicines

| Trade name | Active ingredients | | |
|------------------------------|---------------------------------------|--|--|
| COMIRNATY COVID-19 vaccine | tozinameran | | |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) | | |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) | | |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) | | |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) | | |

■ 1 MedDRA Reaction Terms selected.

Search results

infestations

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

| Medicine summar | List of reports | | | | | | | | | |
|---|---|---|--------|---------------|--|--|--|--|--|--|
| Medicine summary | | | | | | | | | | |
| The medicine summar adverse events. | The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | | | |
| Further information a | bout the medicine summary | | | | | | | | | |
| Information on printing | ng search results | | | | | | | | | |
| Sort by: | | | | rsion of this | | | | | | |
| Number of cases - hi | ghest first | | report | | | | | | | |
| | | | | | | | | | | |
| MedDRA system organ class MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. Number of cases with a single suspected medicine outcome | | | | | | | | | | |
| Infections and | Pneumonia | 1 | 1 | 1 | | | | | | |

Verifiable death

Male – aged undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 527357 | 26/03/2021 | - | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | • <u>Pneumonia</u> |

■ <u>5 medicines selected</u> between 28/03/2021 - 28/03/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | General physical health deterioration | 1 | 1 | 1 |

Verifiable death

Male – aged undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 527894 | 28/03/2021 | - | М | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | General physical health deterioration |

■ <u>5 medicines selected</u> between 29/03/2021 - 29/03/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

 $\overline{}$

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | General physical health deterioration | 1 | 1 | 1 |

Verifiable death

Male – age 93

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 528345 | 29/03/2021 | 93 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Chest pain General physical health deterioration |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

infestations

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple Further information about the medicine summary Information on printing search results Sort by: Print version of this $\overline{}$ Number of cases - highest first MedDRA system MedDRA reaction term **Number of Number of** Number of organ class Click on a term below to search the MedlinePlus medical cases cases with a cases where death was a dictionary. suspected reported medicine outcome Infections and Pneumonia

Verifiable death

Female – age 93

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 528392 | 29/03/2021 | 93 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | • <u>Pneumonia</u> |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

Nervous system

disorders

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

Unresponsive to stimuli

■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report Number of cases - highest first $\overline{}$ MedDRA MedDRA reaction term **Number of Number of Number of** system organ cases with a cases where Click on a term below to search cases class the MedlinePlus medical single death was a reported suspected medicine outcome

Verifiable death

Female – age 97

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 529022 | 30/03/2021 | 97 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Unresponsive to stimuli |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single $\underline{\text{suspected}}$ medicine: $\boldsymbol{1}$

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

List of reports

■ More information on the search results

Medicine summary Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

Verifiable death

Male – age 84

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 529201 | 30/03/2021 | 84 | М | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



Verifiable death

Male – age 94

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 529039 | 30/03/2021 | 94 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Dyspnoea Respiratory rate increased |

Verifiable death –Male - Age 94

Medicine summary - (1 rows)

igchtharpoonup Hover over the table to view exporting data and other options. Click on the dots to see more options. ightharpoonup

| MedDRA system organ class | MedDRA reaction term | Number of cases | Cases with a single suspected medicine | Cases where death was a reported outcome |
|--------------------------------------|----------------------|-----------------|--|--|
| General disorders and administration | Malaise | 1 | 1 | 1 |
| site conditions | | | | |

List of reports - (1 rows)

?

Hover over the table to view exporting data and other options. Click on the dots to see more options. \rightarrow

| Case number ▼ | Report entry date | Age (years) | Gender | Medicines reported as being taken | MedDRA reaction terms |
|----------------------|-------------------|-------------|--------|--|-----------------------|
| 529418 | 31/03/2021 | 91 | Male | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | Malaise |

Age (years)

- Select all
- ☐ 18 to 64
- ✓ 65 and above

Gender

- Select all
- ✓ Male

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

procedural

complications

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

immunisation

■ More information on the search results

| Medicine summary List of reports | | | | | | | | |
|--|--|---|--------|---------------|--|--|--|--|
| Medicine summary | | | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | | |
| Further information abou | ut the medicine summary | | | | | | | |
| Information on printing | Information on printing search results | | | | | | | |
| Sort by: | | | | rsion of this | | | | |
| Number of cases - high | est first | | report | | | | | |
| MedDRA system organ class MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. MedDRA reaction term Click on a term below to search the MedlinePlus medicine Mumber of cases with a cases where death was a reported medicine outcome | | | | | | | | |
| Injury, poisoning and | Adverse event following | 1 | 1 | 1 | | | | |

Verifiable death

Male – age 82

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 530248 | 01/04/2021 | 82 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

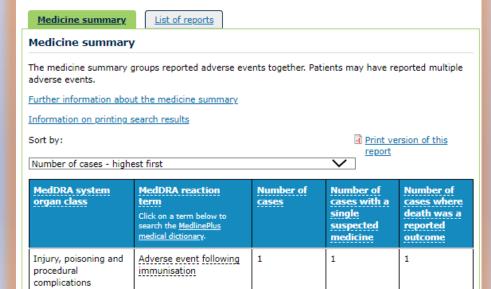
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



Verifiable death

Female – age 72

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 530690 | 02/04/2021 | 72 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summary | List of reports | | | | |
|---|--|-----------------|--|--|--|
| Medicine summary | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | |
| Further information about | <u>Further information about the medicine summary</u> | | | | |
| Information on printing search results | | | | | |
| Sort by: | | | | | |
| Number of cases - highest first | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | |
| General disorders and administration site | Influenza like illness | 1 | 1 | 1 | |

Verifiable death

Female – age 73

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 531359 | 05/04/2021 | 73 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Influenza like illness Injection site reaction |

■ <u>5 medicines selected</u> between 05/04/2021 - 05/04/2021.

Selected medicines

| Trade name | Active ingredients | | |
|------------------------------|---------------------------------------|--|--|
| COMIRNATY COVID-19 vaccine | tozinameran | | |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) | | |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) | | |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) | | |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) | | |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summary | List of reports | | | | |
|---|--|---------------------|--|--|--|
| Medicine summary | | | | | |
| The medicine summary of adverse events. | groups reported adverse eve | ents together. Pati | ents may have re | ported multiple | |
| Further information abou | t the medicine summary | | | | |
| Information on printing s | search results | | | | |
| Sort by: | | | | | |
| Number of cases - highe | est first | | report | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | |
| Respiratory, thoracic and mediastinal disorders | Respiratory failure | 1 | 1 | 1 | |

Verifiable death

Male – age 84

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 531342 | 05/04/2021 | 84 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | DyspnoeaRespiratory failureVomiting |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

Sort by:

The results are shown in two tabs.

Number of cases - highest first

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Fall | 1 | 1 | 1 |

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 531742 | 06/04/2021 | 82 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Fall Hyperhidrosis Hypotension Subdural haemorrhage Unresponsive to stimuli |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: ${f 1}$

More information on the search results

$\underline{\mathsf{Medicine}\;\mathsf{summary}}$

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Cerebral venous thrombosis | 1 | 1 | 1 |

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 532798 | 06/04/2021 | 88 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Atrial fibrillation Cerebral venous thrombosis Intestinal infarction Intestinal ischaemia Mesenteric artery embolism |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

| Med | licin | e su | <u>mma</u> | <u>ry</u> | |
|-----|-------|------|------------|-----------|--|
| | | | | | |

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Gastrointestinal disorders | Erosive oesophagitis | 1 | 1 | 1 |

Verifiable death – Female- Age 71

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 531759 | 06/04/2021 | 71 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Diarrhoea Erosive oesophagitis Malaise |

TOPOTE

Selected medicines

| Trade name | Active ingredients | |
|------------------------------|---------------------------------------|--|
| COMIRNATY COVID-19 vaccine | tozinameran | |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) | |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) | |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) | |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) | |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| _ | MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|------------------------------|---|-----------------|--|--|
| | Hepatobiliary disorders | Gallbladder mass | 1 | 1 | 1 |

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 532108 | 06/04/2021 | 95 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Atrial fibrillation Cerebrovascular accident Gallbladder mass Nausea Pulmonary embolism Tachypnoea Vomiting |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary Medicine summary

<u>List of reports</u>

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Loss of consciousness | 1 | 1 | 1 |

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 532790 | 06/04/2021 | 82 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Loss of consciousness |

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 26

Number of cases with a single <u>suspected</u> medicine: **26**Number of cases where <u>death</u> was a reported outcome: **1**

■ More information on the search results

Medicine summary List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Pyrexia | 26 | 26 | 1 |

Verifiable death- Male – age 96

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 536534 | 13/04/2021 | 96 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | • <u>Pyrexia</u> |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

dictionary.

Cyanosis

Vascular disorders

■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Sort by: Print version of this report Number of cases - highest first $\overline{}$ MedDRA MedDRA reaction term **Number of Number of** Number of system organ cases cases with a cases where Click on a term below to search death was a class the MedlinePlus medical single

reported

outcome

suspected medicine

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 533147 | 07/04/2021 | 82 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | CyanosisDyspnoeaRespiratory distress |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Depressed level of consciousness | 1 | 1 | 1 |

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 533668 | 08/04/2021 | 90 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Depressed level of consciousness |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary Medicine summary

List of reports

The medicine summary groups reported adverse events together. Patients may have reported multiple

adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Pulmonary congestion | 1 | 1 | 1 |

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 534410 | 09/04/2021 | 100 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Dyspnoea General physical health deterioration Malaise Oxygen saturation decreased Pulmonary congestion |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

disorders

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single <u>suspected</u> medicine: 1

Number of cases where <u>death</u> was a reported outcome: 1

■ More information on the search results

| Medicine summa | List of reports | | | | | | | |
|---------------------------------|---|-----------------|--|--|--|--|--|--|
| Medicine summ | Medicine summary | | | | | | | |
| The medicine summa | The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | |
| Further information a | about the medicine summary | | | | | | | |
| Information on printi | ing search results | | | | | | | |
| Sort by: | | | | rsion of this | | | | |
| Number of cases - h | nighest first | | report | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | |
| Nervous system | Haemorrhage intracranial | 1 | 1 | 1 | | | | |

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 534327 | 09/04/2021 | 76 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Tradename not specified (temazepam) - Not suspected Crestor (rosuvastatin calcium) - Not suspected Micardis (telmisartan) - Not suspected Xarelto (rivaroxaban) - Not suspected | Confusional state Haemorrhage intracranial Hypotension Meningitis Nausea Sepsis Vomiting |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Encephalopathy | 1 | 1 | 1 |

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 534960 | 09/04/2021 | 75 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | DysarthriaEncephalopathyLethargySeizureVomiting |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Pulmonary embolism | 1 | 1 | 1 |

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 535193 | 10/04/2021 | 77 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | • <u>Pulmonary</u> <u>embolism</u> |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

Sort by:

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Number of cases - highest first

report V

Print version of this

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|---|-----------------|--|--|
| Musculoskeletal and connective tissue disorders | Tenosynovitis stenosans | 1 | 1 | 1 |

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 535185 | 10/04/2021 | 83 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Arthralgia Tenosynovitis stenosans |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summary | List of reports | | | | | | | |
|--|---|-----------------|--|--|--|--|--|--|
| Medicine summary | | | | | | | | |
| The medicine summary gro adverse events. | The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | |
| Further information about | the medicine summary | | | | | | | |
| Information on printing se | arch results | | | | | | | |
| Sort by: | | | | rsion of this | | | | |
| Number of cases - highest | t first | | report | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | |
| General disorders and administration site conditions | Disease progression | 1 | 1 | 1 | | | | |

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 536304 | 12/04/2021 | 86 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Disease progression |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort b

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|-----------------------------|--|-----------------|--|--|
| Infections and infestations | Sepsis | 1 | 1 | 1 |

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 535523 | 12/04/2021 | 91 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Chest pain Dyspnoea Myocardial infarction Nausea Sepsis Unresponsive to stimuli |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results



Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 535903 | 12/04/2021 | 89 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Cardiac arrest |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

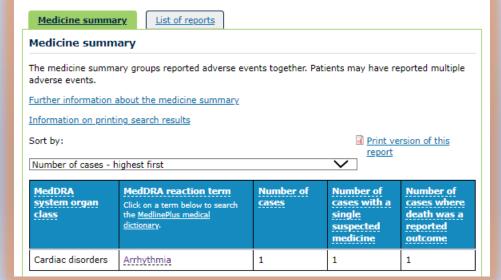
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 535669 | 12/04/2021 | 94 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Arrhythmia |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Respiratory, thoracic and mediastinal disorders

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

| Medicine summary | List of reports | | | | | | | | |
|-------------------------------------|---|-----------------|--|--|--|--|--|--|--|
| Medicine summa | Medicine summary | | | | | | | | |
| The medicine summar adverse events. | The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | | |
| Further information ab | out the medicine summary | | | | | | | | |
| Information on printin | g search results | | | | | | | | |
| Sort by: | Sort by: | | | | | | | | |
| Number of cases - hig | hest first | | V | | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | | |

Pulmonary oedema

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 535750 | 12/04/2021 | 75 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Dyspnoea Loss of consciousness Pulmonary oedema |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected,

Search results

complications

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results



Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 535733 | 12/04/2021 | 87 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

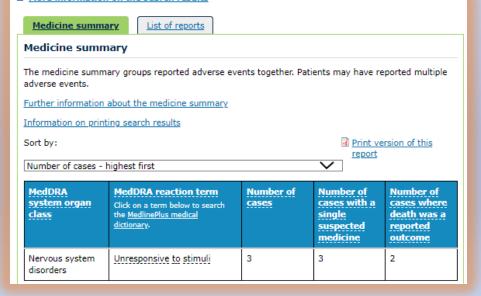
The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 2

More information on the search results



Verifiable death

Female – age 80

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 535872 | 12/04/2021 | 80 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Unresponsive to stimuli |

Of the 3 that reported this reaction, the other person
Can be cross referenced as another death, the 3rd
Person reported other reactions that a death
Was NOT reported for, meaning this person
Was the second death of 3 persons with this reaction

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summ | List of reports | | | | | | | |
|---------------------------------|--|---------------------|--|--|--|--|--|--|
| Medicine summary | | | | | | | | |
| adverse events. | about the medicine summary | ents together. Pati | ents may have re | ported multiple | | | | |
| Information on prin | ting search results | | | | | | | |
| Sort by: | | | | | | | | |
| Number of cases - | highest first | | report | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | |
| Nervous system disorders | Unresponsive to stimuli | 1 | 1 | 1 | | | | |

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 536914 | 13/04/2021 | 92 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Unresponsive to stimuli |

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 536538 | 13/04/2021 | 81 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|---|-----------------|--|--|
| Infections and infestations | Pneumonia aspiration | 1 | 1 | 1 |

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 537556 | 14/04/2021 | 80 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected Tradename not specified (atorvastatin) - Not suspected Tradename not specified (colchicine) - Not suspected Tradename not specified (perindopril) - Not suspected Bisoprolol (bisoprolol fumarate) - Not suspected Eliquis (apixaban) - Not suspected Keflex (cefalexin monohydrate) - Not suspected Panadeine Forte (codeine phosphate hemihydrate; paracetamol) - Not suspected | Pneumonia aspiration Small intestinal obstruction Vomiting |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Medicine summary

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

List of reports

■ More information on the search results

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Renal and urinary disorders | Renal ischaemia | 1 | 1 | 1 |

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 537212 | 14/04/2021 | 48 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Antiphospholipid syndrome Embolism Fibrin D dimer increased Multiple organ dysfunction syndrome Pulmonary embolism Renal ischaemia Thrombocytopenia Thrombosis Thrombosis with thrombocytopenia syndrome Visceral venous thrombosis |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: 1

List of reports

■ More information on the search results

Medicine summary

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Skin and subcutaneous tissue disorders | Night sweats | 1 | 1 | 1 |

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 537472 | 14/04/2021 | 40 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Lexapro (escitalopram) - Not suspected Valium (diazepam) - Not suspected Zypine (olanzapine) - Not suspected Zyprexa Zydis (olanzapine) - Not suspected | Decreased appetite Night sweats Pyrexia Urinary incontinence |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: ${\bf 2}$

Number of cases where death was a reported outcome: 2

More information on the search results

Medicine summary List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

" '

Number of cases - highest first

Sort by:

| | ત | Print: | version | of | this |
|---------------|---|--------|---------|----|------|
| | | repor | t | | |
| $\overline{}$ | 1 | | | | |

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|---|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 2 | 2 | 2 |

Verifiable death

1 - Male – age 752 - 88 – sex undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 537100 | 14/04/2021 | 75 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |
| 537408 | 14/04/2021 | 88 | - | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Unresponsive to stimuli | 1 | 1 | 1 |

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 538304 | 15/04/2021 | 86 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Agonal respiration Haemorrhage intracranial Hypertension Paraesthesia Unresponsive to stimuli |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

Investigations

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

List of reports Medicine summary Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Sort by: Print version of this report $\overline{}$ Number of cases - highest first MedDRA reaction term MedDRA system **Number of Number of** Number of organ class cases with a cases where cases Click on a term below to search the MedlinePlus medical single death was a dictionary. reported suspected medicine outcome

Platelet count decreased

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 537952 | 15/04/2021 | 94 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Abdominal pain Arthralgia Back pain Pain in extremity Platelet count decreased Pulmonary embolism Thrombosis Vomiting |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

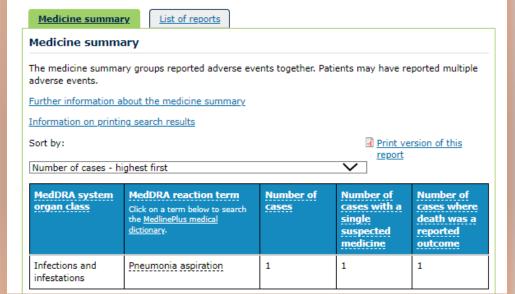
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



Verifiable death

Female – age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 538596 | 16/04/2021 | - | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Pneumonia aspiration |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

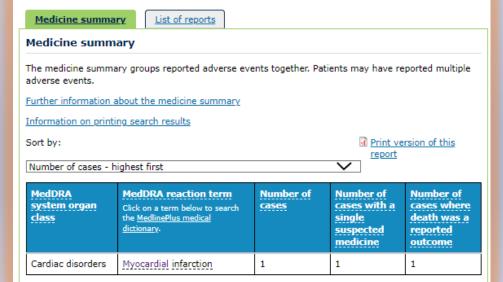
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 538583 | 16/04/2021 | 88 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Fall Myocardial infarction |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Infections and infestations | Pneumonia | 1 | 1 | 1 |

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 538589 | 16/04/2021 | 92 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | • Pneumonia |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 538825 | 16/04/2021 | 40 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Abdominal pain Cardiac arrest Dyspnoea Pulmonary embolism Sepsis Vomiting |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Death | 1 | 1 | 1 |

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 538635 | 16/04/2021 | 96 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation Death Malaise |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 2 | 2 | 2 |

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 538648 | 16/04/2021 | 62 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation Injection site reaction |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|---|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

Verifiable death

Female – age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 539580 | 18/04/2021 | - | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

- 5 medicines selected between 18/04/2021 18/04/2021.
- 2 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 5

Number of cases with a single suspected medicine: 5

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Pulmonary embolism | 3 | 3 | 1 |
| Vascular disorders | Deep vein thrombosis | 3 | 3 | 1 |

Verifiable death

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 539588 | 18/04/2021 | 73 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Deep vein thrombosis Pulmonary embolism |

■ 5 medicines selected between 19/04/2021 - 19/04/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

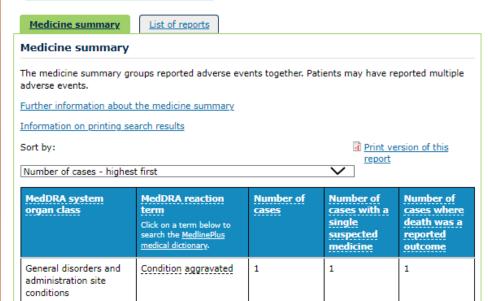
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



Verifiable death

Female – age 88

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 540158 | 19/04/2021 | 88 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebral infarction Condition aggravated Microangiopathic haemolytic anaemia Thrombocytopenia |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

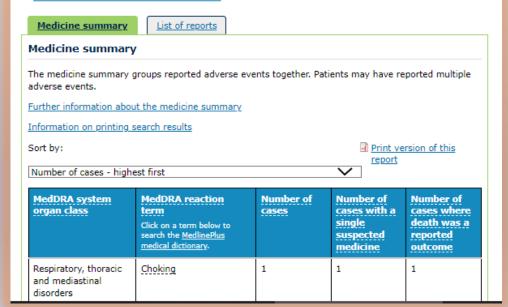
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results



Verifiable death

Female – age 94

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 540031 | 19/04/2021 | 94 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebrovascular accident Choking Loss of consciousness |

■ 5 medicines selected between 19/04/2021 - 19/04/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results



Verifiable death

Male – age 73

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 540025 | 19/04/2021 | 73 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardiac arrest Demyelinating polyneuropathy Guillain-Barre syndrome |

■ 5 medicines selected between 19/04/2021 - 19/04/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

List of reports

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Hemiparesis | 1 | 1 | 1 |

Verifiable death

Female – age 91

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 540106 | 19/04/2021 | 91 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Decreased appetiteFacial paralysisHemiparesisLethargy |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

| Medicine summ | <u>iary</u> | List of reports | | | |
|-----------------------------------|-------------|---|----------------------|--|--|
| Medicine sumr | nary | | | | |
| The medicine sumn adverse events. | nary gro | ups reported adverse (| events together. Pai | tients may have re | eported multiple |
| Further information | about t | he medicine summary | | | |
| Information on prin | nting sea | rch results | | | |
| Sort by: | | | | Print ve | ersion of this |
| Number of cases - | highest | first | | report | |
| MedDRA system organ class | Click on | RA reaction term a term below to search linePlus medical dictionary | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
| Nervous system disorders | | disseminated nalomyelitis | 1 | 1 | 1 |

Verifiable death

Male – age 63

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 540014 | 19/04/2021 | 63 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Acute disseminated encephalomyelitis |

■ 5 medicines selected between 19/04/2021 - 19/04/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single <u>suspected</u> medicine: 1

Number of cases where <u>death</u> was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|---|-----------------|--|--|
| Infections and infestations | Pneumonia | 1 | 1 | 1 |

Verifiable death

Male – age 81

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 539979 | 19/04/2021 | 81 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | • <u>Pneumonia</u> |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this

Number of cases - highest first

| Number of cases - highest first | | | | | | | |
|---------------------------------|--|-----------------|--|--|--|--|--|
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | |
| Nervous system disorders | Ischaemic stroke | 1 | 1 | 1 | | | |

Verifiable death

Female – age 91

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 539728 | 19/04/2021 | 91 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Dysarthria Ischaemic stroke Lethargy Loss of consciousness |

■ 5 medicines selected between 19/04/2021 - 19/04/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | General physical health deterioration | 1 | 1 | 1 |

Verifiable death

Female – age 93

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 539895 | 19/04/2021 | 93 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | General physical health deterioration |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Blood and lymphatic system disorders | Anaemia | 1 | 1 | 1 |

Verifiable death

Male – age 83

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 539888 | 19/04/2021 | 83 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Anaemia Concomitant disease progression Pulmonary embolism Thrombocytopenia |

■ 5 medicines selected between 19/04/2021 - 19/04/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

More information on the search results

<u>Medicine summary</u>

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 2 | 2 | 2 |

Verifiable death

Male – age 87

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 539893 | 19/04/2021 | 87 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Concomitant disease progression |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of

<u>List of reports</u>

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 1 | 1 |

Verifiable death

Female – age 100

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 540595 | 20/04/2021 | 100 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Concomitant disease progression |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results



Verifiable death

Female – age 92

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 540763 | 20/04/2021 | 92 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Hypotension Loss of consciousness Nausea Pain |

Hypotension, Nausea & Pain where also reported With a death associated, therefore this case is the One that resulted in death with loss of consciousness

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiogenic shock | 1 | 1 | 1 |

Verifiable death

Male – age 91

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 541331 | 21/04/2021 | 91 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Cardiogenic shock |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



Verifiable death

Female – age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 541389 | 21/04/2021 | - | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Decreased appetite Dysphagia |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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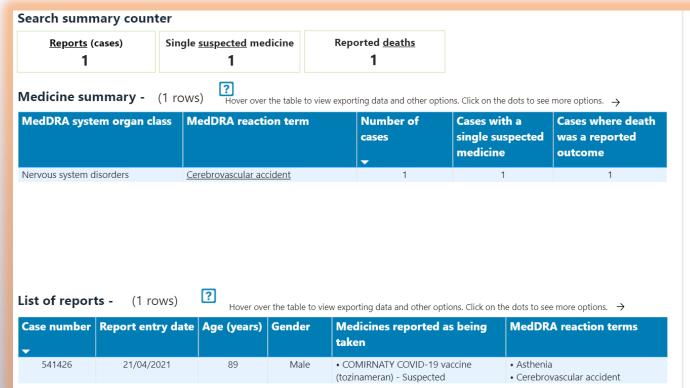
Number of cases - highest first

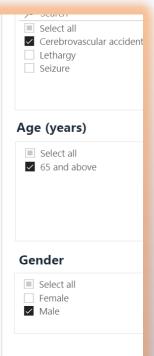
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|---|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

Verifiable death

Female – age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 541534 | 21/04/2021 | 82 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |





| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 541426 | 21/04/2021 | 89 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Asthenia Cerebrovascular accident |

5 medicines selected between 21/04/2021 - 21/04/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

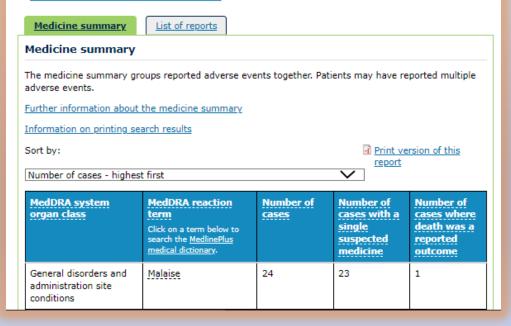
The results are shown in two tabs.

Number of reports (cases): 24

Number of cases with a single suspected medicine: 23

Number of cases where death was a reported outcome: 1

More information on the search results



Verifiable death - Male – age 71

| Case numb | Report er entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|--------------|-------------------------|--------------|--------|--|---|
| 54168 | 2 21/04/2021 | 71 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | MalaiseVomiting |

we know this is the case that had a death reported also as their other reaction (vomiting) also had a death associated and we can filter for age / vaccine / sex with BETA DAEN. The other option (after filtering) had other reactions NOT associated with a death

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 5

Number of cases with a single suspected medicine: 4

Number of cases where death was a reported outcome: 5

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

 $\overline{}$

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | |
|--|--|-----------------|--|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 5 | 4 | 5 | |

- 1. Verifiable deaths Female age 88
- 2. Verifiable deaths Female age 97
- 3. Verifiable deaths Female age 95
- 4. Verifiable deaths Female age 94
- 5. Verifiable deaths Female age 90

| | | | | | report |
|----------------|----------------------|--------------|--------|--|---|
| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
| 541883 | 22/04/2021 | 88 | F | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected Tradename not specified (Product not coded) - Not suspected Coveram 10mg/5mg (perindopril arginine; amlodipine besilate) - Not suspected Diabex (metformin hydrochloride) - Not suspected | Adverse event following immunisation |
| 542196 | 22/04/2021 | 97 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |
| 542230 | 22/04/2021 | 95 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |
| 542243 | 22/04/2021 | 94 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |
| 542302 | 22/04/2021 | 90 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 542222 | 22/04/2021 | 85 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Depressed level of consciousness |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

| Medicine summa | List of reports | | | |
|----------------------------------|---|-------------------|--|--|
| Medicine sumn | nary | | | |
| The medicine summadverse events. | ary groups reported adverse ev | ents together. Pa | tients may have re | eported multiple |
| urther information | about the medicine summary | | | |
| information on print | ting search results | | | |
| Sort by: | | | | ersion of this |
| Number of cases - | highest first | | report | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
| Cardiae diserders | Myocardial icchaemia | 1 | , | , |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 542385 | 22/04/2021 | 76 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cold sweat Coronary artery disease Dyspnoea Headache Hypertension Influenza like illness Myocardial ischaemia Seizure |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

Gastrointestinal

disorders

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

Intestinal obstruction

■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: Number of cases - highest first ~ MedDRA reaction term **Number of Number of** Number of MedDRA system organ class cases with a cases where Click on a term below to cases search the MedlinePlus single death was a medical dictionary. suspected reported

medicine

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 542206 | 22/04/2021 | 83 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Intestinal obstruction |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

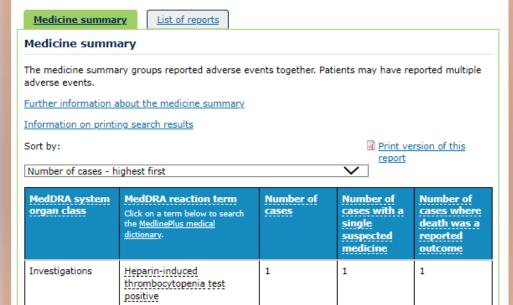
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 542174 | 22/04/2021 | 55 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Heparin-induced thrombocytopenia test positive Pulmonary embolism Thrombocytopenia |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 8

connective tissue disorders

Number of cases with a single suspected medicine: 8

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple Further information about the medicine summary Information on printing search results Print version of this Sort by: $\overline{}$ Number of cases - highest first Number of MedDRA system MedDRA reaction Number of Number of cases where organ class cases cases with a term death was a Click on a term below to search the MedlinePlus suspected reported medical dictionary. medicine outcome Musculoskeletal and Back pain

Verifiable death Female – age 74

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 542323 | 22/04/2021 | 74 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Back painChest painDyspnoea |

We can deduce that this is one of the eleven deaths reported on 22/4. These three symptoms are the remaining symptoms for a person that died through a process of elimination of symptoms

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summ | List of reports | | | |
|----------------------------------|---|--------------------|--|--|
| Medicine sumn | nary | | | |
| The medicine summadverse events. | nary groups reported adverse ev | ents together. Pat | ients may have re | ported multiple |
| Further information | about the medicine summary | | | |
| Information on prin | ting search results | | | |
| Sort by: | | | Print ve | rsion of this |
| Number of cases - | highest first | | ~ | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
| Nervous system disorders | Dysarthria | 2 | 2 | 1 |

Verifiable death Male – age 71

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 542726 | 23/04/2021 | 71 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | DiarrhoeaDysarthriaVomiting |

We know this was one of the two deaths reported on 23/4 because they reported 3 symptoms that had a death associated with them (no other person had these 3 symptoms)

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

List of reports

■ More information on the search results

Medicine summary

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by: Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|---|-----------------|--|--|
| Investigations | Platelet count decreased | 1 | 1 | 1 |

 $\overline{}$

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 543110 | 25/04/2021 | 88 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Anaemia Fibrin D dimer increased Platelet count decreased Sepsis |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

disorders

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

| Medicine summ | List of reports | | | |
|-----------------------------------|---|--------------------|--|--|
| Medicine sumr | nary | | | |
| The medicine sumn adverse events. | nary groups reported adverse e | vents together. Pa | tients may have re | eported multiple |
| Further information | about the medicine summary | | | |
| Information on prin | ting search results | | | |
| Sort by: | | | | ersion of this |
| Number of cases - | highest first | | report | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
| Nervous system | Cerebrovascular accident | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 543115 | 25/04/2021 | 82 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebrovascular accident |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

Infections and

infestations

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

Pneumonia aspiration

■ More information on the search results

List of reports Medicine summary Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Sort by: Print version of this report Number of cases - highest first $\overline{\mathsf{v}}$ MedDRA system MedDRA reaction term **Number of Number of** Number of cases with a organ class cases where cases Click on a term below to search the MedlinePlus medical death was a single dictionary. suspected reported medicine outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 543225 | 26/04/2021 | 73 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Hypotension Pneumonia aspiration Respiratory failure |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Injury, poisoning and procedural

complications

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

medical dictionary.

immunisation

Adverse event following

More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report Number of cases - highest first $\overline{}$ Number of MedDRA system MedDRA reaction **Number of Number of** cases with a cases where organ class term cases death was a Click on a term below to search the MedlinePlus single reported

medicine

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 543311 | 26/04/2021 | 100 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summary | List of reports | | | | | | | |
|---|--|-----------------|--|--|--|--|--|--|
| Medicine summary | | | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary | | | | | | | | |
| Information on printing | ·- | | | | | | | |
| Sort by: | Sort by: Print version of this report | | | | | | | |
| Number of cases - high | est first | | <u> </u> | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | |
| Skin and subcutaneous tissue disorders | Toxic epidermal necrolysis | 1 | 1 | 1 | | | | |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 543278 | 26/04/2021 | 91 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | BlisterLethargyRashToxic epidermal necrolysis |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summary | List of reports |
|------------------|-----------------|
| | |

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Number of cases - highest first

Sort by:

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|----------------------------------|--|-----------------|--|--|
| Injury, poisoning and procedural | Subdural haemorrhage | 1 | 1 | 1 |

Print version of this

report

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 543362 | 26/04/2021 | 82 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Fall Subdural haemorrhage |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where $\underline{\text{death}}$ was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this

Number of cases - highest first

| Number of cases - II | ignest first | | | |
|---------------------------------|---|-----------------|--|--|
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 543246 | 26/04/2021 | 87 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Atrioventricular block Cardiac arrest Vomiting |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Vascular disorders | Circulatory collapse | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 543388 | 26/04/2021 | 66 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Circulatory collapseDyspnoeaNauseaVomiting |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Congestive cardiomyopathy | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 543252 | 26/04/2021 | 65 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Congestive cardiomyopathy |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

disorders

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports

| riedicine summary | List of Teports | | | | | | |
|---|--|-----------------|--|--|--|--|--|
| Medicine summary | | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | |
| Further information abo | ut the medicine summary | | | | | | |
| Information on printing | search results | | | | | | |
| Sort by: | | | Print ve | rsion of this | | | |
| North and annual black | | | report | | | | |
| Number of cases - high | est first | | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | |
| Respiratory, thoracic and mediastinal | Respiratory distress | 1 | 1 | 1 | | | |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 543239 | 26/04/2021 | 95 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Respiratory distress Vomiting |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Medicine summary

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

List of reports

More information on the search results

| Medicine summary | |
|--|------------------------------|
| The medicine summary groups reported adverse events together. Patients adverse events. | may have reported multiple |
| Further information about the medicine summary | |
| Information on printing search results | |
| Sort by: | Print version of this report |
| Number of cases - highest first | |

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Loss of consciousness | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 543461 | 26/04/2021 | 92 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Death Loss of consciousness |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this

Number of cases - highest first

| MedDRA syste organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|-----------------------------|--|-----------------|--|--|
| Infections and infestations | Urinary tract infection | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 543358 | 26/04/2021 | 69 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Sepsis Urinary tract infection |

■ <u>5 medicines selected</u> between 26/04/2021 - 26/04/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

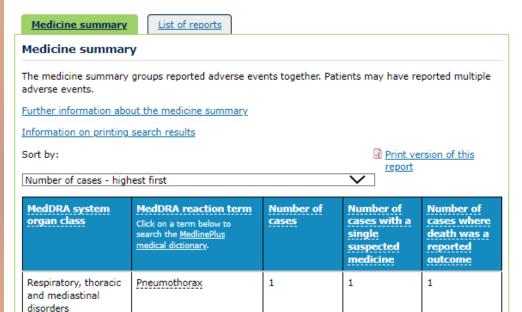
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 543370 | 26/04/2021 | 88 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Fall Pneumothorax |

■ 5 medicines selected between 26/04/2021 - 26/04/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case numb | Report er entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|--------------|-------------------------|--------------|--------|---|---|
| 54335 | 9 26/04/2021 | 87 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | • Arrhythmia |

■ 5 medicines selected between 26/04/2021 - 26/04/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

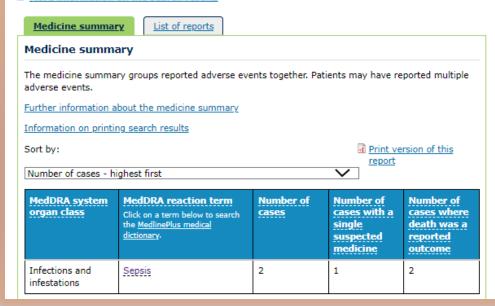
The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 2

More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 543347 | 26/04/2021 | 82 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Depressed level of consciousness Disseminated intravascular coagulation Sepsis |

■ 5 medicines selected between 26/04/2021 - 26/04/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

Sort by:

The results are shown in two tabs.

Number of cases - highest first

Number of reports (cases): 2

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 2

■ More information on the search results

Medicine summary Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results

Print version of this

report

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 2 | 1 | 2 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 543260 | 26/04/2021 | 83 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | ArthralgiaCardiac arrestHeadacheMalaiseSomnolence |

■ 5 medicines selected between 27/04/2021 - 27/04/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Unresponsive to stimuli | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 543839 | 27/04/2021 | 65 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Unresponsive to stimuli |

■ <u>5 medicines selected</u> between 27/04/2021 - 27/04/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|-----------------------------|--|-----------------|--|--|
| Infections and infestations | Septic shock | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 543969 | 27/04/2021 | 72 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Septic shock |

■ <u>5 medicines selected</u> between 28/04/2021 - 28/04/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

Infections and

infestations

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

the MedlinePlus medical

Abdominal sepsis

dictionary.

■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Sort by: Print version of this <u>report</u> $\overline{}$ Number of cases - highest first MedDRA system MedDRA reaction term **Number of** Number of Number of organ class cases with a cases where cases Click on a term below to search

1

death was a

reported

outcome

single

suspected medicine

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 544804 | 28/04/2021 | 85 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Abdominal sepsis Angioedema |

■ <u>5 medicines selected</u> between 28/04/2021 - 28/04/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

disorders

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports

| Medicine summar | у | | | |
|--------------------------------------|--|---------------------|--|--|
| The medicine summary adverse events. | groups reported adverse e | vents together. Pat | ients may have re | ported multiple |
| Further information abo | ut the medicine summary | | | |
| Information on printing | search results | | | |
| Sort by: | | | Print ve | rsion of this |
| Number of cases - high | est first | | report | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
| Respiratory, thoracic | Pulmonary embolism | 3 | 3 | 1 |

Verifiable death Male – age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 544400 | 28/04/2021 | - | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Deep vein thrombosis Pulmonary embolism |

■ 5 medicines selected between 29/04/2021 - 29/04/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Dysarthria | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 544963 | 29/04/2021 | 71 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Dysarthria Influenza like illness Syncope Vomiting |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

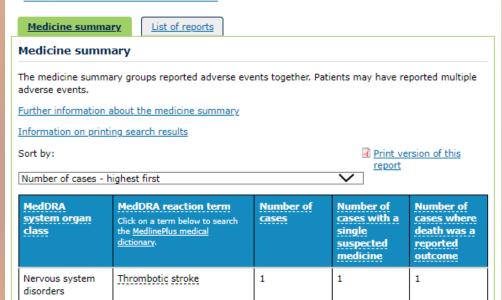
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 546183 | 30/04/2021 | 95 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Thrombotic stroke |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Brain injury | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 545445 | 30/04/2021 | 79 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Brain injury Cardiac arrest Chest pain |

■ <u>5 medicines selected</u> between 30/04/2021 - 30/04/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

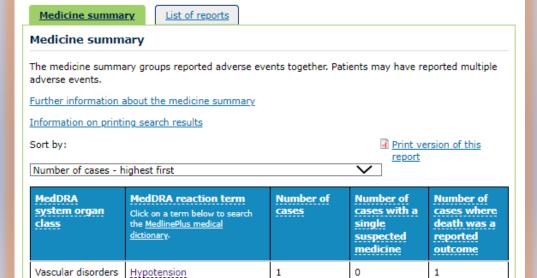
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 546056 | 30/04/2021 | 79 | M | Tradename not specified (Product not coded) - Suspected COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Confusional state Diabetes mellitus Disorientation Fall Hypotension Influenza like illness Loss of consciousness |

■ <u>5 medicines selected</u> between 30/04/2021 - 30/04/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 5

Number of cases with a single suspected medicine: 5

Number of cases where death was a reported outcome: 1

More information on the search results

| Medicine summa | <u>ry</u> <u>List of reports</u> | | | | | | | |
|------------------------------------|---|-----------------|--|--|--|--|--|--|
| Medicine summ | Medicine summary | | | | | | | |
| The medicine summa adverse events. | The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | |
| Further information a | about the medicine summary | | | | | | | |
| Information on printi | ng search results | | | | | | | |
| Sort by: | | | Print ve | rsion of this | | | | |
| Number of cases - h | ighest first | | report | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | |
| Vascular disorders | Deep vein thrombosis | 5 | 5 | 1 | | | | |

Verifiable death Female – age 50

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 546170 | 30/04/2021 | 50 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Deep vein thrombosis Malaise Pulmonary embolism |

We can establish that this person was one of the 5 who's death was registered as the 3 symptoms all had a death associated with them (no other report matched these 3 symptoms)

■ 1 medicine selected between 30/04/2021 - 30/04/2021.

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

The state of the s

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 545654 | 30/04/2021 | 84 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cerebrovascular accident |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Acute myocardial infarction | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 546342 | 01/05/2021 | 81 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Acute myocardial infarction Atrial fibrillation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 3

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Terminal state | 3 | 3 | 3 |

- 1 -Verifiable death Male age 82
- 2 -Verifiable death Female age 85
- 3 Verifiable death Female age 96

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 546503 | 02/05/2021 | 82 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Terminal state |
| 546506 | 02/05/2021 | 85 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Terminal state |
| 546508 | 02/05/2021 | 96 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Terminal state |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

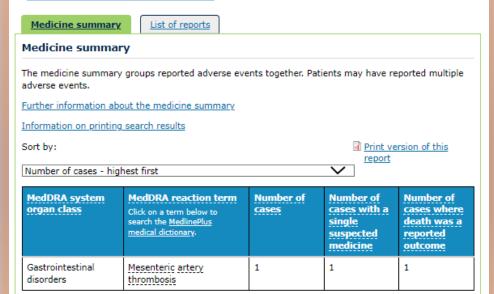
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 546816 | 03/05/2021 | 77 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected Fluad (Influenza virus haemagglutinin) - Not suspected | Blood fibrinogen increased Mesenteric artery thrombosis Pulseless electrical activity |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: ${f 1}$

■ More information on the search results

Medicine summary List o

<u>List of reports</u>

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

 $\overline{}$

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 546651 | 03/05/2021 | 87 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Concomitant disease progression Deep vein thrombosis Peripheral swelling |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine sum | <u>mary</u> | List of | reports |
|--------------|-------------|---------|---------|
| Medicine sum | marv | | |

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Death | 1 | 1 | 1 |

Print version of this

<u>report</u>

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 547096 | 03/05/2021 | 65 | М | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | • <u>Death</u> |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single $\underline{\text{suspected}}$ medicine: $\boldsymbol{0}$

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 546880 | 03/05/2021 | 67 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected FLUAD QUAD (Influenza virus haemagglutinin) - Suspected | Cardiac arrest Myocardial ischaemia |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 2

More information on the search results

List of reports Medicine summary Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Sort by: Print version of this report ~ Number of cases - highest first **Number of** MedDRA system MedDRA reaction Number of Number of organ class cases cases with a cases where term single death was a Click on a term below to search the MedlinePlus suspected reported medical dictionary. medicine outcome General disorders and Peripheral swelling administration site conditions

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 547090 | 03/05/2021 | 79 | М | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected Tradename not specified (allopurinol) - Not suspected Tradename not specified (amlodipine) - Not suspected Tradename not specified (bimatoprost) - Not suspected Tradename not specified (hypromellose) - Not suspected Tradename not specified (hypromellose) - Not suspected Tradename not specified (pantoprazole) - Not suspected Tradename not specified (trimethoprim) - Not suspected Pextran (dextran 70; glucose monohydrate) - Not suspected Pravastatin (pravastatin sodium) - Not suspected Valaciclovir (valaciclovir hydrochloride) - Not suspected | Chest pain Dyspnoea Peripheral swelling Tachycardia |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 2

More information on the search results

List of reports Medicine summary Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple Further information about the medicine summary Information on printing search results Sort by: ☐ Print version of this $\overline{}$ Number of cases - highest first MedDRA system MedDRA reaction **Number of Number of** Number of organ class cases cases with a cases where Click on a term below to death was a search the MedlinePlus suspected reported medical dictionary. medicine outcome General disorders and General physical health administration site deterioration conditions

1 - Verifiable death Female – age 922 - Verifiable death Female – age 95

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 546910 | 03/05/2021 | 92 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | General physical health deterioration Myocardial infarction |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 547083 | 03/05/2021 | 95 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | General physical health deterioration Myocardial infarction |

We Know these are the two deaths associated with General Physical Health Deterioration because the third person also had Lethargy reported which did NOT have a death associated with it

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|---|-----------------|--|--|
| Infections and infestations | Sepsis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 547421 | 04/05/2021 | 95 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Sepsis |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summa | List of reports | | | | | | | | |
|----------------------------------|---|-----------------|--|--|--|--|--|--|--|
| Medicine summary | | | | | | | | | |
| The medicine summadverse events. | The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | | |
| Further information | about the medicine summary | | | | | | | | |
| Information on print | ing search results | | | | | | | | |
| Sort by: | | | | rsion of this | | | | | |
| Number of cases - I | nighest first | | report | | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | | |
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 | | | | | |

Verifiable death Female – age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 547142 | 04/05/2021 | - | F | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Cardiac arrest Chest pain Fatigue |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 2 | 2 | 2 |

1- Verifiable death Female – age 882- Verifiable death Male – age 83

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 547411 | 04/05/2021 | 88 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Adverse event following immunisation |
| 547424 | 04/05/2021 | 83 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${\bf 0}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Atrial flutter | 1 | 0 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 547969 | 05/05/2021 | 77 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected FLUAD QUAD (Influenza virus haemagglutinin) - Suspected | Atrial flutterCardiac arrestPalpitations |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

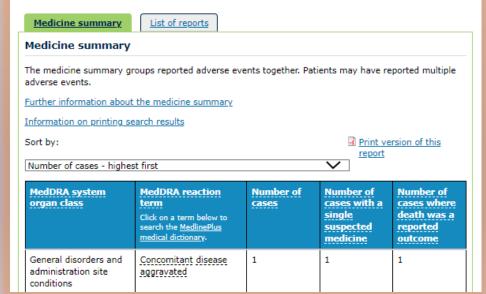
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 548356 | 05/05/2021 | 69 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Concomitant disease aggravated Dyspnoea Pyrexia Somnolence |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Cardiac disorders

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 3

Cardiac arrest

More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Sort by: Print version of this $\overline{}$ Number of cases - highest first MedDRA MedDRA reaction term **Number of Number of Number of** cases with a cases where system organ cases Click on a term below to search class the MedlinePlus medical single death was a dictionary.

suspected

medicine

reported

outcome

1 - Verifiable death Male – age 70

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 548152 | 05/05/2021 | 70 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Cardiac arrest |
| 548338 | 05/05/2021 | 78 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Cardiac arrest Dyspnoea Pulmonary embolism |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report Number of cases - highest first \sim **Number of Number of** MedDRA system MedDRA reaction term organ class Click on a term below to search the MedlinePlus medical cases with a cases where death was a single dictionary. suspected reported medicine outcome Metabolism and Diabetes mellitus nutrition disorders

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 547870 | 05/05/2021 | 80 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Confusional state Diabetes mellitus Disorientation Fall Hypotension Influenza like illness Loss of consciousness |

Selected medicines

| Trade name | Active ingredients | |
|------------------------------|---------------------------------------|--|
| COMIRNATY COVID-19 vaccine | tozinameran | |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) | |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) | |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

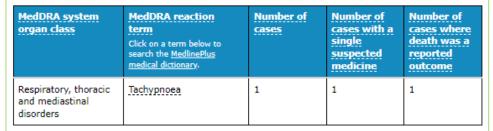
Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 548780 | 06/05/2021 | 57 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Body temperature increased Deep vein thrombosis Dyspnoea Electrocardiogram Headache Hyperglycaemia Loss of consciousness Pulmonary embolism Tachycardia Tachypnoea |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

1 MedDRA Reaction Terms selected.

Search results

Infections and

infestations

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

dictionary.

■ More information on the search results

| Medicine summar | r <u>v</u> | <u>List of reports</u> | | | | | | | | |
|---|------------|---------------------------------------|------|-----------------|-------------------------------------|-----------------------------------|--|--|--|--|
| Medicine summary | | | | | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | | | | |
| Further information a | bout th | e medicine sumn | nary | | | | | | | |
| Information on printing | ng sear | ch results | | | | | | | | |
| Sort by: | | | | | | rsion of this | | | | |
| Number of cases - highest first | | | | | | | | | | |
| MedDRA system organ class | Click o | ORA reaction tern a term below to sed | | Number of cases | Number of cases with a single | Number of cases where death was a | | | | |

suspected

medicine

2

reported

outcome

Verifiable death Female – age 95

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 548513 | 06/05/2021 | 95 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Sepsis |

We can deduce this was the person that died who suffered sepsis as the other person reported other events that were not associated with a death

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 3

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 3 | 3 | 3 |

- 1- Verifiable death Male age 71
- 2 Verifiable death Female age 56
- 3 Verifiable death Female age 86

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 549386 | 07/05/2021 | 71 | М | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |
| 549442 | 07/05/2021 | 56 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Tradename not specified (Product not coded) - Not suspected Buprenorphine (buprenorphine hydrochloride) - Not suspected Endep (amitriptyline hydrochloride) - Not suspected | Adverse event following immunisation |
| 549639 | 07/05/2021 | 86 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: <u>report</u> Number of cases - highest first **Number of Number of** MedDRA system MedDRA reaction term **Number of** organ class cases cases with a cases where Click on a term below to search the MedlinePlus medical single death was a dictionary. suspected reported medicine outcome Infections and Pneumonia aspiration infestations

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 549431 | 07/05/2021 | 83 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | HypophagiaPneumonia aspirationPyrexia |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports **Medicine summary** The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: $\overline{}$ Number of cases - highest first MedDRA Number of **Number of** Number of MedDRA reaction term cases where system organ cases with a Click on a term below to search cases class the MedlinePlus medical single death was a dictionary. suspected reported medicine outcome Cardiac disorders Cardiac arrest

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 549691 | 07/05/2021 | 79 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Cardiac arrest |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Print version of this

Further information about the medicine summary

Information on printing search results

Sort by:

Number of cases - highest first

| | 4edDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|--|-----------------|--|--|
| ē | Seneral disorders and Idministration site Conditions | Oedema peripheral | 1 | 1 | 1 |

| - | Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|---|----------------|----------------------|--------------|--------|--|---|
| | 549073 | 07/05/2021 | 80 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Dyspnoea Oedema peripheral |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

disorders

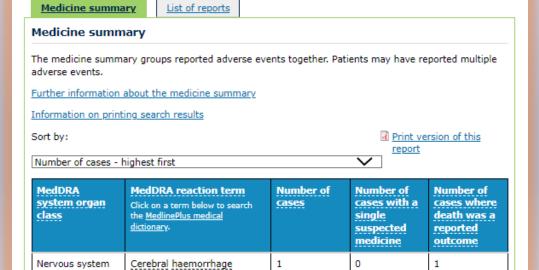
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 549441 | 07/05/2021 | 93 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Xarelto (rivaroxaban) - Suspected | Cerebral haemorrhage |

■ 5 medicines selected between 07/05/2021 - 07/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Cardiac disorders

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Sort by: Print version of this Number of cases - highest first $\overline{}$ MedDRA MedDRA reaction term **Number of Number of** Number of system organ cases cases with a cases where Click on a term below to search class the MedlinePlus medical single death was a suspected reported

Acute myocardial infarction

medicine

outcome

Verifiable death Male – age 78

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 549686 | 07/05/2021 | 78 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Tradename not specified (Product not coded) - Not suspected Tradename not specified (aspirin) - Not suspected Tradename not specified (atorvastatin) - Not suspected Tradename not specified (clopidogrel) - Not suspected Tradename not specified (clopidogrel) - Not suspected Tradename not specified (domperidone) - Not suspected Tradename not specified (irbesartan) - Not suspected Tradename not specified (pantoprazole) - Not suspected Tradename not specified (pantoprazole) - Not suspected Tradename not specified (ranitidine) - Not suspected Tradename not specified (ranitidine) - Not suspected Tradename not specified (ranitidine) - Not suspected Tradename not specified | Acute myocardial infarction Fibrin D dimer increased |

We know that this case was the death reported because they also reported fibrin d-dimer increased which was also associated with a death

■ 5 medicines selected between 10/05/2021 - 10/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

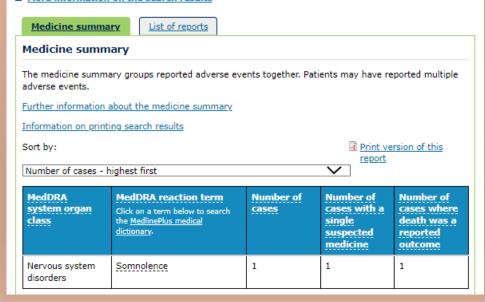
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 550666 | 10/05/2021 | 89 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Concomitant disease aggravated Somnolence Vision blurred |

■ 5 medicines selected between 10/05/2021 - 10/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 550219 | 10/05/2021 | 79 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

■ 5 medicines selected between 11/05/2021 - 11/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 0 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 551047 | 11/05/2021 | 88 | М | Tradename not specified (Product not coded) - Suspected COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Concomitant disease progression Cyanosis Pain Pallor |

■ <u>5 medicines selected</u> between 11/05/2021 - 11/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Infections and infestations | Pneumonia aspiration | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 551017 | 11/05/2021 | 99 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Pneumonia aspiration |

■ <u>5 medicines selected</u> between 11/05/2021 - 11/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single <u>suspected</u> medicine: 1

Number of cases where <u>death</u> was a reported outcome: 2

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Vascular disorders | Cyanosis | 2 | 1 | 2 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 551062 | 11/05/2021 | 77 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cyanosis Dyspnoea |

■ 5 medicines selected between 12/05/2021 - 12/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\boldsymbol{1}$

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Unresponsive to stimuli | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 551850 | 12/05/2021 | 81 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Body temperature decreased Hypotension Hypoxia Unresponsive to stimuli Wheezing |

■ 5 medicines selected between 12/05/2021 - 12/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

 \sim

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

Verifiable death Male – age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 551345 | 12/05/2021 | - | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 12/05/2021 - 12/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Embolic stroke | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 551574 | 12/05/2021 | 83 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cerebral haemorrhage Embolic stroke |

■ <u>5 medicines selected</u> between 12/05/2021 - 12/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summa | <u>ry</u> <u>List of reports</u> | | | | | | | | |
|---|--|-----------------|--|--|--|--|--|--|--|
| Medicine summary | | | | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | | | |
| Further information a | about the medicine summary | | | | | | | | |
| Information on printi | ng search results | | | | | | | | |
| Sort by: | | | | | | | | | |
| Number of cases - h | ighest first | | V | | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | | |
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 | | | | | |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 551568 | 12/05/2021 | 90 | М | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Cardiac arrest |

■ 5 medicines selected between 13/05/2021 - 13/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Medicine summary

General disorders and

administration site

conditions

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

List of reports

Click on a term below to search the <u>MedlinePlus</u>

Concomitant disease

medical dictionary.

progression

■ More information on the search results

| Medicine summary | | | | | | | | | |
|---|----------------------|-----------------|------------------------|-----------------------|--|--|--|--|--|
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | | | |
| Further information about | the medicine summary | | | | | | | | |
| Information on printing se | arch results | | | | | | | | |
| Sort by: | | | ₫ Print ve | rsion of this | | | | | |
| Number of cases - highest first | | | | | | | | | |
| MedDRA system organ class | MedDRA reaction term | Number of cases | Number of cases with a | Number of cases where | | | | | |

death was a

reported

outcome

suspected

medicine

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 552212 | 13/05/2021 | 83 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Concomitant disease progression |

■ 5 medicines selected between 13/05/2021 - 13/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Asphyxia | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 552278 | 13/05/2021 | 71 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | • <u>Asphyxia</u> |

■ <u>5 medicines selected</u> between 14/05/2021 - 14/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Cardiac disorders

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

Cardiac arrest

More information on the search results

| Medicine summa | <u>ry</u> <u>List of reports</u> | | | | | | | | |
|---|---|-----------------|--|--|--|--|--|--|--|
| Medicine summary | | | | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | | | |
| Further information a | about the medicine summary | | | | | | | | |
| Information on printi | ng search results | | | | | | | | |
| Sort by: | Sort by: | | | | | | | | |
| Number of cases - h | ighest first | | ~ | | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | | |

1

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 553016 | 14/05/2021 | 76 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Cardiac arrest Malaise |

■ 5 medicines selected between 14/05/2021 - 14/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

| Number of cases - h | ighest first | | ~ | |
|---------------------|----------------------|-----------|-----------|-----|
| | | | | |
| MedDRA | MedDRA reaction term | Number of | Number of | Num |

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Myocardial infarction | 1 | 1 | 1 |

Print version of this

report

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 553078 | 14/05/2021 | 83 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Agitation Dyspnoea Myocardial infarction |

■ <u>5 medicines selected</u> between 14/05/2021 - 14/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Acute myocardial infarction | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 552770 | 14/05/2021 | 78 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Acute myocardial infarction Concomitant disease aggravated Lethargy Malaise Vomiting |

■ 5 medicines|selected| between 14/05/2021 - 14/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 2 | 2 | 2 |

- 1 Verifiable death Male age 73
- 2 Verifiable death Male age 85

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 553099 | 14/05/2021 | 73 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |
| 553131 | 14/05/2021 | 85 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

■ 5 medicines selected between 15/05/2021 - 15/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|---|-----------------|--|--|
| Infections and infestations | Pneumonia | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 553718 | 15/05/2021 | 83 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | ContusionIncoherentMalaisePneumonia |

■ 5 medicines selected between 16/05/2021 - 16/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



Verifiable death Male – age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 553816 | 16/05/2021 | - | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardiac arrest Cyanosis Hypotension Malaise Right ventricular hypertrophy |

■ <u>5 medicines selected</u> between 17/05/2021 - 17/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Myocardial infarction | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 554151 | 17/05/2021 | 79 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Myocardial infarction |

■ <u>5 medicines selected</u> between 17/05/2021 - 17/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Gastrointestinal disorders | Intestinal obstruction | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 553998 | 17/05/2021 | 90 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Intestinal obstruction Pain Pneumonia aspiration |

■ 5 medicines selected between 17/05/2021 - 17/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|---|-----------------|--|--|
| Investigations | Oxygen saturation decreased | 1 | 0 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 554087 | 17/05/2021 | 70 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected FLUAD QUAD (Influenza virus haemagglutinin) - Suspected | DyspnoeaFood refusalOxygen saturation decreased |

■ 5 medicines selected between 17/05/2021 - 17/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 1

More information on the search results

| Medicine summary | List of reports |
|------------------|-----------------|
| | |

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Number of cases - highest first

Sort by:

Print version of this report

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| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 3 | 3 | 1 |

Verifiable death Female – age 93

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 554002 | 17/05/2021 | 93 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cerebrovascular accident Decreased appetite |

We know this was the person that died of the 3 that suffered this reaction as they also reported decreased appetite

Which also had 1 death associated with it.

■ 5 medicines selected between 17/05/2021 - 17/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 3

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| | MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|--|-----------------|--|--|
| ı | Injury, poisoning and procedural complications | Adverse event following immunisation | 3 | 3 | 3 |

- 1 Verifiable death Male age 88
- 2 Verifiable death Female age 70
 - 3 Verifiable death Male age 70

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 554127 | 17/05/2021 | 88 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Adverse event following immunisation |
| 554142 | 17/05/2021 | 70 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Herceptin (Trastuzumab) - Not suspected Perjeta (Pertuzumab) - Not suspected | Adverse event following immunisation |
| 554165 | 17/05/2021 | 70 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

■ 5 medicines selected between 18/05/2021 - 18/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: ${\bf 2}$

Number of cases where death was a reported outcome: 2

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 2 | 2 | 2 |

1 - Verifiable death Male – age 85

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 554588 | 18/05/2021 | 85 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |
| 554589 | 18/05/2021 | 58 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 18/05/2021 - 18/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|-------------------------------|--|-----------------|--|--|
| Gastrointestinal disorders | Gastrointestinal haemorrhage | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 554700 | 18/05/2021 | 70 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Gastrointestinal haemorrhage |

■ <u>5 medicines selected</u> between 18/05/2021 - 18/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Number of cases - highest first

Print version of this report

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| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Fall | 1 | 0 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 554730 | 18/05/2021 | 90 | M | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Aortic aneurysm rupture Fall Hypotension Traumatic intracranial haemorrhage |

■ 5 medicines selected between 18/05/2021 - 18/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Gastrointestinal disorders | Intestinal perforation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 554711 | 18/05/2021 | 92 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Abdominal pain Intestinal perforation Vomiting |

■ <u>5 medicines selected</u> between 18/05/2021 - 18/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

and mediastinal disorders

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summary | <u>List of reports</u> | | | |
|--------------------------------------|--|--------------------|--|--|
| Medicine summar | у | | | |
| The medicine summary adverse events. | groups reported adverse e | vents together. Pa | tients may have re | eported multiple |
| Further information abo | ut the medicine summary | | | |
| Information on printing | search results | | | |
| Sort by: | | | Print ve | ersion of this |
| Number of cases - high | est first | | ✓ ICDOR | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
| Respiratory, thoracic | Respiratory arrest | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 554665 | 18/05/2021 | 56 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Respiratory arrest |

■ 5 medicines selected between 18/05/2021 - 18/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

Investigations

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

Oxygen saturation decreased

■ More information on the search results

Medicine summary List of reports **Medicine summary** The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Sort by: Print version of this report Number of cases - highest first $\overline{}$ MedDRA system MedDRA reaction term **Number of** Number of Number of cases where organ class cases with a cases Click on a term below to search the MedlinePlus medical single death was a dictionary. reported suspected

medicine

outcome

Verifiable death Female – age 91

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 554503 | 18/05/2021 | 91 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Contusion Cough Dyspnoea Oxygen saturation decreased Wheezing |

We know this was the death that reported Oxygen saturation decreased as their other symptoms all had 1 deaths associated with them also

■ 5 medicines selected between 18/05/2021 - 18/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

disorders

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

Medicine summary List of reports

| ricalenic samm | <u> </u> | | | | | | | |
|--|--|-----------------|--|--|--|--|--|--|
| Medicine summary | | | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported adverse events. | | | | | | | | |
| Further information | Further information about the medicine summary | | | | | | | |
| Information on print | ting search results | | | | | | | |
| Sort by: | | | ₫ Print ve | rsion of this | | | | |
| Number of cases - | highest first | | report | | | | | |
| | I | | | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | |
| Nervous system | Somnolence | 2 | 2 | 1 | | | | |

Verifiable death Female – age 92

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 554579 | 18/05/2021 | 92 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Somnolence |

We know this person who reported somnolence because
The other person that died reported several other reactions
That did not have a death associated with them

■ 1 medicine selected between 19/05/2021 - 19/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary Medicine summary

List of reports

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

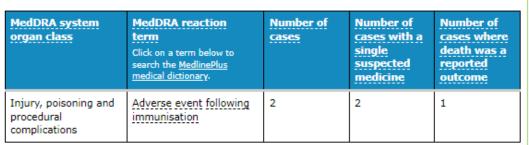
Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first



Verifiable death Female – age 45

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 555334 | 19/05/2021 | 45 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

we know this case had a death reported also as we can filter for age using BETA DAEN

■ 5 medicines selected between 19/05/2021 - 19/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Loss of consciousness | 3 | 3 | 1 |

Verifiable death Female – age 88

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 555025 | 19/05/2021 | 88 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Loss of consciousness Malaise |

we know this case had a death reported also as we can filter for sex using BETA DAEN

■ 1 medicine selected between 19/05/2021 - 19/05/2021.

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single $\underline{\text{suspected}}$ medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Number of cases - highest first

Print version of this report

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 3 | 2 | 1 |

Verifiable death Male – age 75

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 555187 | 19/05/2021 | 75 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cerebrovascular accident |

we know this case had a death reported also as we can filter for sex using BETA DAEN

■ <u>5 medicines selected</u> between 20/05/2021 - 20/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 556062 | 20/05/2021 | 94 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Hyperhidrosis Oxygen saturation decreased |

■ 5 medicines selected between 20/05/2021 - 20/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 2 | 2 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 555741 | 20/05/2021 | 77 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 21/05/2021 - 21/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Carotid artery thrombosis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 556577 | 21/05/2021 | 55 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Arteriosclerosis coronary artery Carotid artery thrombosis Pulmonary embolism |

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single <u>suspected</u> medicine: 1

Number of cases where <u>death</u> was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Cardiac disorders | Myocardial infarction | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 556634 | 21/05/2021 | 92 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Myocardial infarction |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: ${f 1}$

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | |
|----------------------------------|--|-----------------|--|--|--|
| Injury, poisoning and procedural | Adverse event following immunisation | 1 | 1 | 1 | |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 557017 | 23/05/2021 | 60 | М | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

Metabolism and

nutrition disorders

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

the MedlinePlus medical

dictionary.

Hypervolaemia

■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report Number of cases - highest first $\overline{}$ MedDRA system **Number of** MedDRA reaction term **Number of** Number of cases with a cases cases where organ class Click on a term below to search

1

single

suspected medicine death was a reported

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 557543 | 24/05/2021 | 95 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Constipation Hypervolaemia Respiratory failure |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------------|--|--------------------|--|--|
| Respiratory, thoracic and mediastinal | Aspiration | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 557542 | 24/05/2021 | 91 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Aspiration |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

administration site

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

progression

■ More information on the search results

| Medicine summary | <u>List of reports</u> | | | | | | | |
|---|--|---|----------|---|--|--|--|--|
| Medicine summary | | | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | | |
| Further information abou | t the medicine summary | | | | | | | |
| Information on printing s | earch results | | | | | | | |
| Sort by: | Sort by: @ Print version of this report | | | | | | | |
| Number of cases - highe | st first | | <u> </u> | | | | | |
| MedDRA system organ class MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. Number of cases with a cases where death was a reported medicine outcome | | | | | | | | |
| General disorders and | Concomitant disease | 1 | 1 | 1 | | | | |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 557335 | 24/05/2021 | 65 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Concomitant disease progression |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| General disorders and administration site | Disease progression | 1 | 1 | 1 |

Verifiable death Female – age 68

ropore Case Report Gender Medicines reported as MedDRA reaction Age (yrs) being taken number entry date terms Click on a term below to search the MedlinePlus medical dictionary. 557262 24/05/2021 68 F · COMIRNATY COVID- Adverse event 19 vaccine following (tozinameran) immunisation Suspected Disease progression

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 2

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| _ | MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|----------------------------------|--|--------------------|--|--|
| | Injury, poisoning and procedural | Adverse event following immunisation | 2 | 1 | 2 |

1 - Verifiable death – age 98 2 – Verifiable death – Female –age 87

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 557942 | 25/05/2021 | 98 | - | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Adverse event following immunisation |
| 557967 | 25/05/2021 | 87 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected Fluarix (Influenza virus haemagglutinin) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: $\boldsymbol{1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

<u>Medicine summary</u>

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Cardiac disorders | Cardiac failure | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 558047 | 25/05/2021 | 99 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Cardiac failure Pulmonary oedema |

5 medicines selected between 25/05/2021 - 25/05/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

dictionary.

Cardiac disorders

Cardiac valve disease

■ More information on the search results

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical | Number of cases | Number of cases with a single | Number of cases where death was a |
|------------------------------------|---|---------------------|-------------------------------|---|
| Number of cases - h | ighest first | | V ICEDIT | |
| Sort by: | | | Print ve | ersion of this |
| Information on printing | ng search results | | | |
| Further information a | bout the medicine summary | | | |
| The medicine summa adverse events. | ry groups reported adverse e | vents together. Pat | ients may have re | eported multiple |
| Medicine summa | ary | | | |
| Medicine summar | <u>List of reports</u> | | | |

suspected

medicine

reported

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 557946 | 25/05/2021 | 85 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardiac valve disease Myocardial ischaemia |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

List of reports

■ More information on the search results

Medicine summary

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | |
|---------------------------------|--|-----------------|--|--|--|--|--|--|
| Renal and urinary disorders | End stage renal disease | 1 | 1 | 1 | | | | |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 558227 | 25/05/2021 | 68 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebrovascular accident Diabetic ketoacidosis End stage renal disease Myocardial infarction |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| General disorders and administration site | Concomitant disease progression | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 557868 | 25/05/2021 | 89 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Concomitant disease progression |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|----------------------------------|--|-----------------|--|--|
| Injury, poisoning and procedural | Adverse event following immunisation | 2 | 2 | 2 |

- 1- Verifiable death Male -age 69
- 2- Verifiable death Male –age 52

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 558587 | 26/05/2021 | 69 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |
| 558636 | 26/05/2021 | 52 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Vascular disorders | Aortic aneurysm rupture | 1 | 0 | 1 |

| <u>Case</u> number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|-----------------------|----------------------|--------------|--------|--|--|
| 558522 | 26/05/2021 | 80 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected Fluvax (Influenza virus haemagglutinin) - Suspected | Aortic aneurysm rupture Chest discomfort Condition aggravated Malaise |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------------|---|-----------------|--|--|
| Metabolism and nutrition disorders | Dehydration | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 558781 | 26/05/2021 | 95 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | DehydrationDyspnoeaHeart rate increased |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| General disorders and administration site | Concomitant disease progression | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 558350 | 26/05/2021 | 83 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease progression Deep vein thrombosis Pulmonary embolism |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

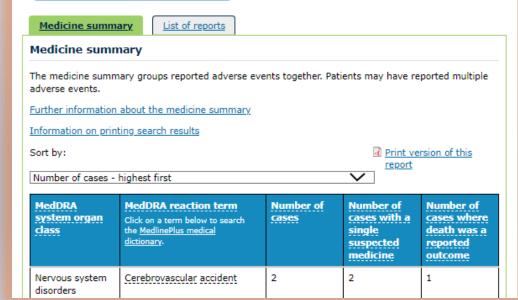
The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results



Verifiable death – Female –age 70

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 558689 | 26/05/2021 | 70 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cerebrovascular accident |

This can be verified as the death that suffered this reaction as the other had vertigo reported also which was not a reaction associated with a death

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Cardiac disorders

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

Myocardial infarction

More information on the search results

Medicine summary List of reports

| redictife Suffilliary | List of reports | | | | | | | |
|---|---|-----------------|--|--|--|--|--|--|
| Medicine summary | | | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | | |
| Further information ab | out the medicine summary | | | | | | | |
| Information on printing | g_search_results | | | | | | | |
| Sort by: Print version of this report | | | | | | | | |
| Number of cases - hig | jhest first | | ~ | | | | | |
| system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | |

Verifiable death – Female –age 91

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 558353 | 26/05/2021 | 91 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Myocardial infarction |

This can be verified as the death that suffered this reaction as the other reported 3 other reactions also which were not reactions associated with a death

- <u>5 medicines selected</u> between 26/05/2021 26/05/2021.
- 3 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 80

Number of cases with a single <u>suspected</u> medicine: **79**Number of cases where <u>death</u> was a reported outcome: **2**

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Fatigue | 49 | 49 | 1 |
| Nervous system disorders | Dizziness | 36 | 36 | 1 |
| General disorders and administration site conditions | Malaise | 18 | 17 | 2 |

Verifiable death – Male –age 71

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 558667 | 26/05/2021 | 71 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Dizziness Fatigue Malaise |

This can be verified as the death from 1/80 as they are the only one that suffered these 3 reactions which were all associated with a death (the other death was also verified by a different reaction)

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Infections and | Pneumonia aspiration | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 559367 | 27/05/2021 | 79 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Pneumonia aspiration |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Myocardial infarction | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 559053 | 27/05/2021 | 78 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Myocardial infarction |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| General disorders and administration site | Concomitant disease progression | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 559232 | 27/05/2021 | 71 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease progression |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



Verifiable death – Male –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 559992 | 28/05/2021 | | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Abdominal pain Abdominal rigidity Abdominal rigidity Abdominal tenderness Acidosis Blood pressure decreased Coma scale abnormal General physical health deterioration Haemodynamic instability Hypophagia Hypotension Hypothermia Malaise Peripheral circulatory failure Peripheral coldness |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report Number of cases - highest first $\overline{}$ MedDRA **Number of Number of** Number of **MedDRA reaction term** system organ Click on a term below to search cases cases with a cases where class the MedlinePlus medical death was a single dictionary. suspected reported medicine outcome Cardiac disorders Acute myocardial infarction

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 560506 | 30/05/2021 | 68 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Acute myocardial infarction |

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Vascular disorders | Deep vein thrombosis | 2 | 2 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 560481 | 30/05/2021 | 82 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Deep vein thrombosis Pulmonary embolism |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 6

Number of cases with a single suspected medicine: 6

Number of cases where death was a reported outcome: 6

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|----------------------------------|--|-----------------|--|--|
| Injury, poisoning and procedural | Adverse event following immunisation | 6 | 6 | 6 |

- 1 Verifiable death Male -age 43
- 2 Verifiable death Male -age 75
- 3 Verifiable death Female -age 74
- 4 Verifiable death Male -age 89
- 5 Verifiable death Male -age 67
- 6 Verifiable death Female -age 55

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 560741 | 31/05/2021 | 43 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Adverse event following immunisation |
| 561074 | 31/05/2021 | 75 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |
| 561111 | 31/05/2021 | 74 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |
| 561179 | 31/05/2021 | 89 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Adverse event following immunisation Fall |
| 561193 | 31/05/2021 | 67 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |
| 561253 | 31/05/2021 | 55 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

Blood and

lymphatic system

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

the MedlinePlus medical

Acquired haemophilia

dictionary.

More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: Number of cases - highest first $\overline{}$ **Number of** Number of MedDRA system MedDRA reaction term Number of cases with a cases where organ class cases Click on a term below to search

single

suspected

medicine

death was a

reported

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 561020 | 31/05/2021 | 96 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Acquired haemophilia |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

 $\overline{}$

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Renal and urinary disorders | Renal failure | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 561128 | 31/05/2021 | 88 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Blood pressure abnormal Fatigue Hyperkalaemia Myalgia Renal failure Retching Vision blurred |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDF system class | tA 1 organ | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--------------------------|----------------|---|-----------------|--|--|
| Nervou disorde | s system rs | Unresponsive to stimuli | 2 | 2 | 1 |

Verifiable death – Male –age 92

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 561188 | 31/05/2021 | 92 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Dyspnoea Unresponsive to stimuli |

We know that this is the death in this reaction category because their other reaction term had a death associated with it too

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 6

Number of cases with a single suspected medicine: 6

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summ | List of reports | | | |
|---------------------------------|--|---------------------|--|--|
| Medicine sumn | nary | | | |
| adverse events. | ary groups reported adverse ever | ents together. Pati | ents may have re | ported multiple |
| Information on print | | | | |
| Sort by: | | | Print ve report | rsion of this |
| Number of cases - | highest first | | V | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
| Blood and lymphatic system | Thrombocytopenia | 6 | 6 | 1 |

Verifiable death – Male –age 73

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 561318 | 31/05/2021 | 73 | M | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Fibrin D dimer increased Thrombocytopenia |

We know that this is the death in this reaction category because their other reaction term had 1 death associated with it too

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Vascular disorders | Capillary leak syndrome | 1 | 1 | 1 |

| <u>Case</u> number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|-----------------------|----------------------|--------------|--------|---|--|
| 562118 | 01/06/2021 | 78 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Capillary leak syndrome Fatigue Multiple organ dysfunction syndrome Myalgia Polycythaemia Syncope Thrombocytopenia |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: ${f 1}$

More information on the search results

| Medicine summa | List of reports | | | | | | |
|---------------------------------|---|---------------------|--|--|--|--|--|
| Medicine summ | Medicine summary | | | | | | |
| adverse events. | ary groups reported adverse ever | ents together. Pati | ents may have re | ported multiple | | | |
| Information on print | | | | | | | |
| Sort by: | | | Print ve report | rsion of this | | | |
| Number of cases - h | nighest first | | V | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | |
| Nervous system disorders | Subarachnoid haemorrhage | 1 | 1 | 1 | | | |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 561794 | 01/06/2021 | 67 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Subarachnoid haemorrhage |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

Vascular disorders

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

dictionary.

Arteriosclerosis

■ More information on the search results

| Medicine summa | <u>ary</u> | <u>List of reports</u> | | | | | |
|---|------------|--------------------------------------|-------------|-----------------|-------------------------------|-----------------------------------|--|
| Medicine sumn | nary | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | |
| Further information | about t | he medicine summ | <u>iary</u> | | | | |
| Information on print | ting sea | rch results | | | | | |
| Sort by: | | | | | | rsion of this | |
| Number of cases - | highest | first | | | report | | |
| MedDRA system organ | Click or | RA reaction tern a term below to sea | | Number of cases | Number of cases with a single | Number of cases where death was a | |

suspected

medicine

reported

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 561920 | 01/06/2021 | 96 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Arteriosclerosis Concomitant disease progression Urinary tract infection |

■ 5 medicines selected between 02/06/2021 - 02/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

| | - 1 | - | | | |
|-------|-------|-------|-------|------|-------|
| IVI 6 | ווווי | cine | - EII | ımım | ary |
| 1.10 | - | CITIC | | | ICI Y |

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site | Hypothermia | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 562466 | 02/06/2021 | 96 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Hypothermia |

■ 5 medicines selected between 02/06/2021 - 02/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

 $\overline{}$

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Ageusia | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 562554 | 02/06/2021 | 66 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Ageusia Anosmia Asthenia Cough Dizziness Fibrin D dimer increased Guillain-Barre syndrome Headache Lethargy Paraesthesia Rash |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: 1

More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 561837 | 01/06/2021 | 80 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Aortic aneurysm rupture |

Selected medicines

| Trade name | Active ingredients | |
|------------------------------|---------------------------------------|--|
| COMIRNATY COVID-19 vaccine | tozinameran | |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) | |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) | |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) | |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) | |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 5

Number of cases with a single suspected medicine: 4

Number of cases where death was a reported outcome: 5

■ More information on the search results

| Medicine summary | <u>List of reports</u> | | | | | | |
|--|---|-----------------|--|--|--|--|--|
| Medicine summary | | | | | | | |
| The medicine summary gadverse events. | The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | |
| Further information abou | Further information about the medicine summary | | | | | | |
| Information on printing s | Information on printing search results | | | | | | |
| Sort by: | Sort by: | | | | | | |
| Number of cases - highest first | | | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | |
| Injury, poisoning and procedural complications | Adverse event following immunisation | 5 | 4 | 5 | | | |

- 1- Verifiable death Male –age 61
- 2- Verifiable death Male –age 89
- 3- Verifiable death Male –age 59
- 4- Verifiable death Male –age 68
- 5- Verifiable death Female -age 70

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 562888 | 03/06/2021 | 61 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |
| 562926 | 03/06/2021 | 89 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |
| 562970 | 03/06/2021 | 59 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |
| 563050 | 03/06/2021 | 68 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |
| 563126 | 03/06/2021 | 70 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Herceptin (Trastuzumab) - Suspected Perjeta (Pertuzumab) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Vascular disorders | Aortic aneurysm | 1 | 1 | 1 |

Verifiable death – Male –age undisclosed

| <u>Case</u> number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|-----------------------|----------------------|--------------|--------|--|--|
| 562980 | 03/06/2021 | - | М | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Aortic aneurysm |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

| Medicine summa | List of reports | | | | | | | |
|---|---|-----------------|--|--|--|--|--|--|
| Medicine summary | | | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | | |
| Further information | about the medicine summary | | | | | | | |
| Information on print | ing search results | | | | | | | |
| Sort by: | | | Print ve | rsion of this | | | | |
| Number of cases - highest first | | | | | | | | |
| Trainber of cases | nignest first | | • | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 563022 | 03/06/2021 | 86 | М | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | Arteriosclerosis coronary artery Arthralgia Chest pain Malaise Vomiting |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Cerebral infarction | 1 | 1 | 1 |

Verifiable death – Male –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 563009 | 03/06/2021 | - | М | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | • <u>Cerebral</u> <u>infarction</u> |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

Sort by:

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

<u>'</u>

Number of cases - highest first

Print version of this report

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Vascular disorders | Aneurysm | 1 | 1 | 1 |

Verifiable death – Female –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 563271 | 03/06/2021 | - | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Aneurysm Headache |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|----------------------------------|--|-----------------|--|--|
| Injury, poisoning and procedural | Toxicity to various agents | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 563015 | 03/06/2021 | 73 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Intentional overdose Thrombosis Toxicity to various agents |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

List of reports

More information on the search results

Medicine summary

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site | Multiple organ dysfunction syndrome | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 563058 | 03/06/2021 | 92 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Multiple organ dysfunction syndrome |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Unresponsive to stimuli | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 563267 | 03/06/2021 | 71 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Faecal vomiting Myocardial infarction Unresponsive to stimuli |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Medicine summary

Cardiac disorders

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

List of reports

Myocardial ischaemia

■ More information on the search results

Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Sort by: Print version of this report Number of cases - highest first $\overline{}$ MedDRA MedDRA reaction term **Number of** Number of **Number of** system organ cases with a cases where cases Click on a term below to search class the MedlinePlus medical single death was a dictionary. suspected reported medicine outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 563055 | 03/06/2021 | 69 | М | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | Malaise Myocardial ischaemia Pain in extremity |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summary | <u>List of reports</u> |
|------------------|------------------------|
| | |

Medicine summary

Sort by:

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system | Depressed level of | 1 | 1 | 1 |

Print version of this

report

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 562988 | 03/06/2021 | 94 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Depressed level of consciousness Hypotension |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal | Pulmonary thrombosis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 563002 | 03/06/2021 | 70 | F | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | Deep vein thrombosis Pulmonary thrombosis |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------------|--|--------------------|--|--|
| Respiratory, thoracic and mediastinal | Wheezing | 3 | 3 | 1 |

Verifiable death – Male –age 72

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 563272 | 03/06/2021 | 72 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | DyspnoeaFatigueWheezing |

We know this entry for wheezing was the one that had a death reported as the other symptoms also had a death associated with them

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|---|--------------------|--|--|
| Psychiatric disorders | Delirium | 1 | 1 | 1 |

Verifiable death – Female –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 563420 | 04/06/2021 | - | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Confusional state Delirium Pulmonary embolism Urinary tract infection |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

| Medicine summar | List of reports | | | | | | | | |
|------------------------------------|---|-----------------|--|--|--|--|--|--|--|
| Medicine summa | Medicine summary | | | | | | | | |
| The medicine summa adverse events. | The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | | |
| Further information a | bout the medicine summary | | | | | | | | |
| Information on printing | ng search results | | | | | | | | |
| Sort by: | | | | rsion of this | | | | | |
| Number of cases - hi | ghest first | | report | | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | | |
| Infections and infestations | Peritonitis | 1 | 1 | 1 | | | | | |

Verifiable death – Female –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 563526 | 04/06/2021 | - | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Appendicitis Peritonitis |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

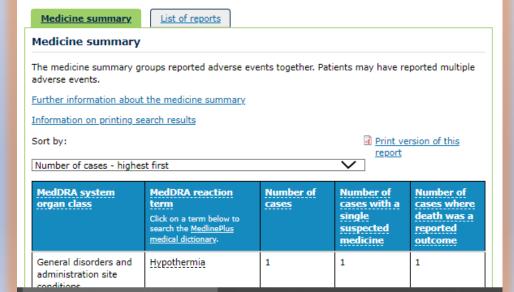
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 563500 | 04/06/2021 | 93 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Hypotension Hypothermia |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 4

Injury, poisoning and

procedural

Number of cases with a single suspected medicine: 4

Number of cases where death was a reported outcome: 3

medical dictionary.

immunisation

Adverse event following

■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report Number of cases - highest first MedDRA system MedDRA reaction **Number of Number of** Number of organ class cases with a cases where cases death was a Click on a term below to single search the MedlinePlus suspected reported

medicine

outcome

Verifiable death – Male –age 91

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 563514 | 04/06/2021 | 91 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation Pneumonia |

Pneumonia also reported which only has
1 death associated with this reaction
So we know this was 1 of the 3 deaths for AEFI

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 2 | 2 | 2 |

1 - Verifiable death - Female -age 82

1 - Verifiable death - Female -age 92

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 563665 | 04/06/2021 | 82 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation Cerebrovascular accident |
| 563694 | 04/06/2021 | 92 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected Tradename not specified (Product not coded) - Not suspected | Cerebrovascular accident |

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Pulmonary embolism | 1 | 1 | 1 |

Verifiable death – Female –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 563420 | 04/06/2021 | - | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Confusional state Delirium Pulmonary embolism Urinary tract infection |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

Verifiable death – Female –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 563423 | 04/06/2021 | - | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|----------------------------------|--|-----------------|--|--|
| Injury, poisoning and procedural | Adverse event following immunisation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 564539 | 07/06/2021 | 91 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|--------------------|--|--|
| General disorders and administration site | Disease progression | 1 | 1 | 1 |

Verifiable death – Male –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 564420 | 07/06/2021 | - | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Disease progression |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| medicine outcome | MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported |
|------------------|---------------------------|---|-----------------|--|---|
| | disorders | haemorrhage | | | |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 564913 | 07/06/2021 | 77 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Upper gastrointestinal haemorrhage |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 3

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| General disorders and administration site | Concomitant disease progression | 3 | 3 | 3 |

- 1- Verifiable death Female –age 76
- 2- Verifiable death Female -age 90
- 3- Verifiable death Female –age 77

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 565076 | 08/06/2021 | 76 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease progression Feeling cold Headache |
| 565154 | 08/06/2021 | 90 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Concomitant disease aggravated Concomitant disease progression Constipation Deep vein thrombosis Fibrin D dimer increased Heparin-induced thrombocytopenia Thrombocytopenia |
| 565335 | 08/06/2021 | 77 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease progression |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

disorders

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

■ More information on the search results

| Medicine summ | List of reports | | | | | | | |
|--------------------------------------|---|--------------------|--|--|--|--|--|--|
| Medicine summary | | | | | | | | |
| The medicine sumn adverse events. | nary groups reported adverse ev | ents together. Pat | ients may have re | ported multiple | | | | |
| Further information | about the medicine summary | | | | | | | |
| Information on prin | ting search results | | | | | | | |
| Sort by: | | | | rsion of this | | | | |
| Number of cases - | highest first | | report | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | |
| Nervous system | Cerebrovascular accident | 2 | 2 | 2 | | | | |

1- Verifiable death – Male –age 69

2- Verifiable death – Female –age 54

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 565016 | 08/06/2021 | 69 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebrovascular accident |
| 565173 | 08/06/2021 | 54 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebrovascular accident Chest pain Vomiting |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Cardiac disorders | Arteriosclerosis coronary artery | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 565235 | 08/06/2021 | 80 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Arteriosclerosis coronary artery |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| edDRA system gan class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|----------------------------|--|-----------------|--|--|
| astrointestinal sorders | Mesenteric vein thrombosis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 565088 | 08/06/2021 | 54 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Mesenteric vein thrombosis |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

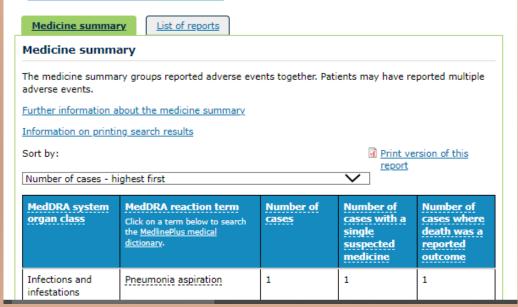
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 565411 | 08/06/2021 | 93 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Pneumonia aspirationVomiting |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

system organ

Cardiac disorders

class

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

| Medicine summa | List of reports | | | |
|------------------------------------|--------------------------------|---------------------|--------------------|-----------------|
| Medicine summ | ary | | | |
| The medicine summa adverse events. | ary groups reported adverse ev | ents together. Pati | ients may have re | ported multiple |
| Further information a | about the medicine summary | | | |
| Information on printi | ng search results | | | |
| Sort by: | | | Print ve report | rsion of this |
| Number of cases - h | ighest first | | ~ | |
| MedDRA | MedDRA reaction term | Number of | Number of | Number of |

cases

Click on a term below to search

the MedlinePlus medical

dictionary.

Cardiac arrest

cases with a

suspected

medicine

single

cases where

death was a

reported

outcome

| Case numbe | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|---------------|----------------------|--------------|--------|--|--|
| 565261 | 08/06/2021 | 57 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Cardiac arrestInjection site pain |

Verifiable death – Male –age 75

| Search summary cou | ınter | | | | | > Search Select all |
|--------------------------------------|--|--|---|--|--|--|
| Reports (cases) 1 Medicine summary | Single suspected me 1 (1 rows) Phover over | dicine Reporte the table to view exporting of | d <u>deaths</u> 1 data and other optio | ns. Click on the dots to see | more options. \rightarrow | □ Arteriosclerosis coronary artery □ Atrial fibrillation ☑ Myocardial infarction □ Palpitations □ Pericarditis |
| MedDRA system organ | class MedDRA react | | umber of ses | Cases with a single suspected medicine | Cases where death was a reported outcome | Age (years) Select all 65 and above |
| Cardiac disorders | Myocardial infarction | <u>on</u> | 1 | 1 | 1 | os and above |
| | | | | | | Gender |
| | | er the table to view exporting | | | • | ■ Select all □ Female ■ Male |
| Case number Report € | entry date Age (years) | Gender Medici taken | nes reported a | s being MedDR | A reaction terms | |
| 565366 8/06 | /2021 75 | | -19 Vaccine AstraZ€ -1-S (Viral vector)) - | , | dial infarction | |

we know this is the case that had a death reported also as we can filter for gender using BETA DAEN

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Cerebral haemorrhage | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 565804 | 09/06/2021 | 52 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebral haemorrhage Cerebral venous sinus thrombosis Fibrin D dimer increased Headache Platelet count decreased Thrombocytopenia Thrombosis with thrombocytopenia syndrome |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiomegaly | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 565884 | 09/06/2021 | 57 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardiomegaly |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single <u>suspected</u> medicine: **1**Number of cases where <u>death</u> was a reported outcome: **1**

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Gastrointestinal disorders | Rectal haemorrhage | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 565833 | 09/06/2021 | 94 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Dyspnoea Rash Rectal haemorrhage |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

List of reports

More information on the search results

| Medicine summary | | |
|------------------|---|--|
| Medicine summary | , | |

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Acute cardiac event | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 565715 | 09/06/2021 | 60 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Acute cardiac event Pulmonary embolism |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Number of cases - highest first

Sort by:

Print version of this report

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| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Cardiac disorders | Cardiac failure | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 565693 | 09/06/2021 | 84 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cardiac failure Contusion Dyspnoea Lethargy Pain in extremity Unresponsive to stimuli |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary Medicine summary

<u>List of reports</u>

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Number of cases - highest first

Sort by:

Print version of this report

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MedDRA MedDRA reaction term Number of Number of Number of cases with a cases where system organ Click on a term below to search class single death was a the MedlinePlus medical suspected reported medicine outcome Vascular disorders | Thrombosis 2

Verifiable death – Female –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 565717 | 09/06/2021 | - | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | • Thrombosis |

We know this is the case that death was associated with because the other case had a large number of of other reactions not associated with death

Verifiable death – Male –age 87

| Search summa | ary counter | | | | | | Select all |
|-------------------------------------|--|----------------------------|-------------------------|--|--|---|---|
| Reports (ca 1 Medicine sum | | e <u>suspected</u> medi 1 | | Reported <u>deaths</u> 1 Approximately the second seco | ons Click on the dats to see | more options. $\rightarrow \qquad \nabla \; \mathbb{R}^3$ | ✓ Adverse event following ☐ Contusion ☐ Medication error ☐ Off label use |
| MedDRA systen | , | MedDRA reactio | | Number of cases | Cases with a single suspected medicine | Cases where death was a reported outcome | Age (years) Select all 65 and above |
| Injury, poisoning and complications | d procedural | Adverse event follow | <u>ring immunisatio</u> | | 1 | 1 | 63 and above |
| | | | | | | | Gender |
| List of reports | Select allFemaleMale | | | | | | |
| Case number R | Report entry dat | e Age (years) | | Medicines reported a aken | s being MedDR | A reaction terms | |
| 565698 | 9/06/2021 | 87 | | COVID-19 Vaccine AstraZ ChAdOx1-S (Viral vector)) | | event following tion | |

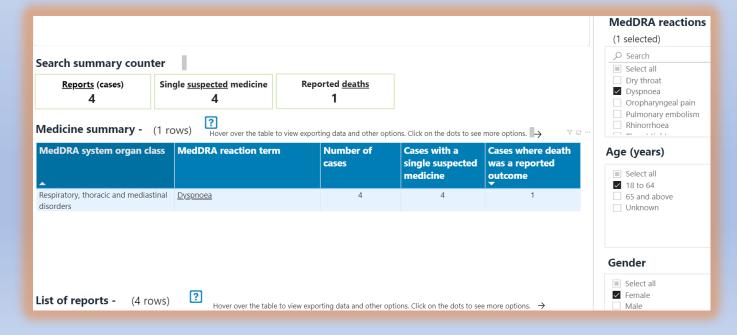
We know this is the case that had a death reported also as we can filter for gender using BETA DAEN

Verifiable death – age undisclosed (1 of these cases had a death reported also)

| Reports (| cases) Singl | e <u>suspected</u> medic 2 | cine | Reported <u>deaths</u> 1 | | | Chest discomfort Chest pain Chills ✓ Concomitant disease aggravated |
|-----------------------------------|----------------------|-------------------------------|-------------------|--|--|---|--|
| Medicine sur MedDRA syste | ` ` | MedDRA reaction | | Number of cases | Cases with a single suspected medicine | c more options. → Cases where death was a reported outcome | Age (years) Select all 18 to 64 |
| General disorders site conditions | and administration | Concomitant disease | <u>aggravated</u> | 2 | 2 | 1 | ✓ Unknown |
| | | | | | | | Gender |
| List of repor | ts - (2 rows) | ? Hover over t | the table to view | exporting data and other opt | ions. Click on the dots to se | ee more options. 🔿 | ■ Select all ✓ Female |
| Case number ▼ | Report entry date | e Age (years) (| | Medicines reported a taken | as being MedDR | A reaction terms | |
| 566222 | 9/06/2021 | - | | COVID-19 Vaccine AstraZ (ChAdOx1-S (Viral vector)) | | nitant disease aggravated | |
| 566159 | 9/06/2021 | - | | COVID-19 Vaccine AstraZ (ChAdOx1-S (Viral vector)) | | nitant disease aggravated | |

Verifiable death – Female – Age 62





| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 565897 | 09/06/2021 | 62 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Dyspnoea |

We know this is the case that had a death reported also as we can filter using BETA DAEN and the other 3 cases had other reactions reported that did not have a death associated with them

■ <u>5 medicines selected</u> between 10/06/2021 - 10/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 566295 | 10/06/2021 | 91 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Acute myocardial infarction Confusional state Dyspnoea Myocardial ischaemia Pain in extremity |

■ 1 medicine selected between 10/06/2021 - 10/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|---|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

| | Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|---|----------------|----------------------|--------------|--------|---|---|
| 5 | 566310 | 10/06/2021 | 86 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 11/06/2021 - 11/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDR system class | | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--------------------------|------------|--|--------------------|--|--|
| Renal ar | nd urinary | Acute kidney injury | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 567054 | 11/06/2021 | 76 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Acute kidney injury Atrial fibrillation Diarrhoea Hypertension Sepsis Syncope |

■ <u>5 medicines selected</u> between 11/06/2021 - 11/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

administration site

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

progression

■ More information on the search results

| Medicine summary | <u>List of reports</u> | | | | | | |
|---|------------------------|-----------|-----------|----------------|--|--|--|
| Medicine summary | | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | |
| Further information about | t the medicine summary | | | | | | |
| Information on printing s | earch results | | | | | | |
| Sort by: | | | | ersion of this | | | |
| Number of cases - highe | st first | | report | | | | |
| MadDDA sustans | MadDDA spection | Number of | Number of | Number of | | | |
| MedDRA system organ class MedDRA reaction term Number of cases Number of cases with a cases where Click on a term below to search the MedlinePlus medical dictionary. Suspected medicine reported outcome | | | | | | | |
| General disorders and | Concomitant disease | 1 | 1 | 1 | | | |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 566936 | 11/06/2021 | 70 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Chest pain Concomitant disease progression Dyspnoea |

■ 1 medicine selected between 11/06/2021 - 11/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------|---------------------------------------|
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |

1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first



| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 567288 | 11/06/2021 | 68 | М | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | Adverse event following immunisation |





■ <u>5 medicines selected</u> between 12/06/2021 - 12/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: ${f 1}$

■ More information on the search results

| Medicine summa | List of reports | | | |
|------------------------------------|---|--------------------|--|--|
| Medicine summ | ary | | | |
| The medicine summa adverse events. | ary groups reported adverse ev | ents together. Pat | ients may have re | ported multiple |
| Further information a | about the medicine summary | | | |
| <u>Information on printi</u> | ng search results | | | |
| Sort by: | | | | rsion of this |
| Number of cases - h | ighest first | | report | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
| Vascular disorders | Cyanosis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 567655 | 12/06/2021 | 80 | M | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected Tradename not specified (Product not coded) - Not suspected | Asthenia Cyanosis Hallucination Unresponsive to stimuli |

■ <u>5 medicines selected</u> between 14/06/2021 - 14/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

General disorders and

administration site

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

Multiple organ dysfunction syndrome

More information on the search results

| Medicine summary List of reports | | | | | | | | | |
|---|---|-----------------|--|--|--|--|--|--|--|
| Medicine summary | | | | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | | | |
| Further information about | the medicine summar | EX. | | | | | | | |
| Information on printing se | arch results | | | | | | | | |
| Sort by: | | | Print ve | rsion of this | | | | | |
| Number of cases - highes | t first | | ~ | | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | | |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 568387 | 14/06/2021 | 83 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Dysarthria Multiple organ dysfunction syndrome Pneumonia |

■ 5 medicines selected between 14/06/2021 - 14/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Eye disorders | Opsoclonus myoclonus | 1 | 0 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 568200 | 14/06/2021 | 74 | F | Tradename not specified (Product not coded) - Suspected COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Encephalitis Fibrin D dimer increased Headache Heparin-induced thrombocytopenia Neoplasm malignant Opsoclonus myoclonus Pulmonary sarcoidosis |

■ <u>5 medicines selected</u> between 14/06/2021 - 14/06/2021.

Selected medicines

| Trade name | Active ingredients | |
|------------------------------|---------------------------------------|--|
| COMIRNATY COVID-19 vaccine | tozinameran | |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) | |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) | |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) | |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) | |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summary | | |
|------------------|--|--|
|------------------|--|--|

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|----------------------------------|--|-----------------|--|--|
| Injury, poisoning and procedural | Adverse event following immunisation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 567973 | 14/06/2021 | 91 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 15/06/2021 - 15/06/2021.

Selected medicines

| Trade name | Active ingredients | |
|------------------------------|---------------------------------------|--|
| COMIRNATY COVID-19 vaccine | tozinameran | |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) | |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) | |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) | |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) | |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

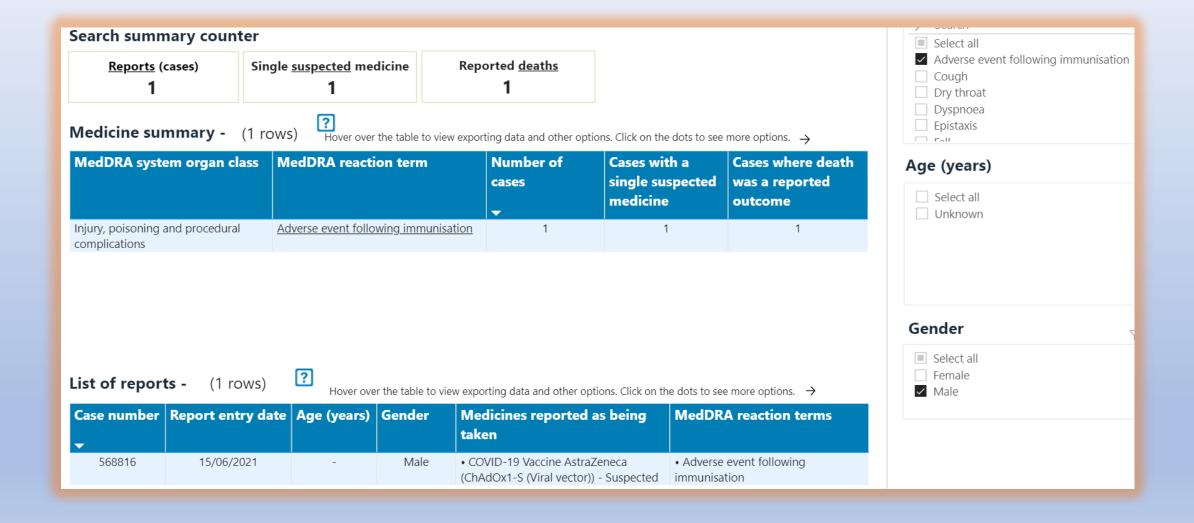
Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summar | <u>List of reports</u> | | | | | | | |
|---|---|-----------------|--|--|---|--|--|--|
| Medicine summa | ary | | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | | |
| Further information about the medicine summary | | | | | | | | |
| Information on printing | ng search results | | | | | | | |
| Sort by: | | | | rsion of this | | | | |
| Number of cases - hi | ghest first | | report | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | |
| Infections and infestations | Upper respiratory tract infection | 1 | 1 | 1 | L | | | |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 568784 | 15/06/2021 | 71 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Hepatorenal failure Rash Systemic candida Thrombocytopenia Upper respiratory tract infection |

Verifiable death – Male –age undisclosed



■ 5 medicines selected between 15/06/2021 - 15/06/2021.

Selected medicines

| Trade name | Active ingredients | | |
|------------------------------|---------------------------------------|--|--|
| COMIRNATY COVID-19 vaccine | tozinameran | | |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) | | |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) | | |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) | | |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) | | |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

MedDRA system

lymphatic system

organ class

Blood and

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

MedDRA reaction term

dictionary.

coagulation

Click on a term below to search the MedlinePlus medical

Disseminated intravascular

More information on the search results

Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Sort by: Print version of this report Number of cases - highest first

Number of

cases

Number of

suspected medicine

single

cases with a

Number of

cases where

death was a

reported

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 568802 | 15/06/2021 | 69 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Disseminated intravascular coagulation Meningococcal sepsis |

■ 5 medicines selected between 15/06/2021 - 15/06/2021.

Selected medicines

| Trade name | Active ingredients | | |
|------------------------------|---------------------------------------|--|--|
| COMIRNATY COVID-19 vaccine | tozinameran | | |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) | | |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) | | |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) | | |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) | | |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 6

Number of cases with a single suspected medicine: 6

Number of cases where death was a reported outcome: 1

More information on the search results

$\underline{\mathsf{Medicine}\;\mathsf{summary}}$

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------------|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal | Pulmonary embolism | 6 | 6 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 568584 | 15/06/2021 | 64 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Pulmonary embolism |

■ <u>5 medicines selected</u> between 16/06/2021 - 16/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Haemorrhage intracranial | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 569553 | 16/06/2021 | 60 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Haemorrhage intracranial |

■ <u>5 medicines selected</u> between 16/06/2021 - 16/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|-------------------------------|---|-----------------|--|--|
| Gastrointestinal disorders | Pancreatitis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 569534 | 16/06/2021 | 72 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Candida sepsis Cholelithiasis Intestinal ischaemia Multiple organ dysfunction syndrome Pancreatitis |

■ 5 medicines selected between 16/06/2021 - 16/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| | MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|-----|------------------------------|---|-----------------|--|--|
| - 1 | Infections and infestations | Encephalitis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 569189 | 16/06/2021 | 88 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | • Encephalitis |

■ 1 medicine selected between 16/06/2021 - 16/06/2021.

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|---|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | nediastinal | | 0 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 569171 | 16/06/2021 | 86 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | • Pulmonary embolism |

■ 5 medicines selected between 17/06/2021 - 17/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

■ More information on the search results

Medicine summary

<u>List of reports</u>

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|----------------------------------|--|-----------------|--|--|
| Injury, poisoning and procedural | Adverse event following immunisation | 2 | 2 | 2 |

1 - Verifiable death - Female -age 67

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 569882 | 17/06/2021 | 67 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |
| 570076 | 17/06/2021 | 73 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

■ 5 medicines selected between 17/06/2021 - 17/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|---|-----------------|--|--|
| Infections and infestations | Pneumonia aspiration | 1 | 1 | 1 |

Verifiable death – Female –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 569816 | 17/06/2021 | - | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Confusional state Decreased appetite Fatigue Pneumonia aspiration |

■ <u>5 medicines selected</u> between 17/06/2021 - 17/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Respiratory, thoracic

and mediastinal

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

Respiratory failure

More information on the search results

Medicine summary List of reports

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | |
|---|--|-----------------|--|--|--|--|--|
| Number of cases - hig | hest first | | ~ | | | | |
| Sort by: | | | Print ve report | ersion of this | | | |
| Information on printing search results | | | | | | | |
| Further information ab | out the medicine summary | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | |
| Medicine summa | ry | | | | | | |
| | | | | | | | |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 570053 | 17/06/2021 | 80 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Respiratory failure |

■ 1 medicine selected between 17/06/2021 - 17/06/2021.

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 2

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------------|--|-----------------|--|--|
| Metabolism and nutrition disorders | Decreased appetite | 3 | 3 | 2 |

Verifiable death – Female –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 569819 | 17/06/2021 | - | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Decreased appetite Fatigue |

■ 5 medicines selected between 18/06/2021 - 18/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

More information on the search results

| Medicine summary | <u>List of reports</u> | | | | | | | |
|--------------------------------------|---|---------------------|--|--|--|--|--|--|
| Medicine summary | | | | | | | | |
| The medicine summary adverse events. | groups reported adverse eve | ents together. Pati | ients may have re | ported multiple | | | | |
| Further information abou | ut the medicine summary | | | | | | | |
| Information on printing | search results | | | | | | | |
| Sort by: | | | Print ve | ersion of this | | | | |
| Number of cases - high | est first | | V | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | |
| | | | | | | | | |

1- Verifiable death – Male –age 852- Verifiable death – Female –age 92

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 571121 | 18/06/2021 | 85 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |
| 571278 | 18/06/2021 | 92 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation Fall |

■ <u>5 medicines selected</u> between 18/06/2021 - 18/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

<u>Medicine summary</u>

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 570789 | 18/06/2021 | 90 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardiac arrestDecreased appetiteHypotensionLethargyMalaise |

■ 5 medicines selected between 18/06/2021 - 18/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 1

■ More information on the search results

<u>Medicine summary</u>

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

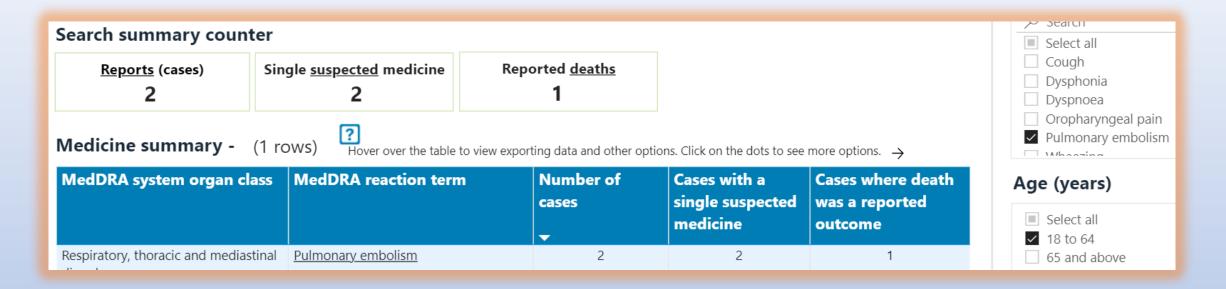
Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Ataxia | 3 | 3 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 570818 | 18/06/2021 | 81 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Ataxia Guillain-Barre syndrome |

Verifiable death – Male –age 59



| List of repor | ts - (2 rows) | Hover ove | er the table to view | w exporting data and other options. Click on th | e dots to see more options. → |
|---------------|----------------------|-------------|----------------------|---|---|
| Case number | Report entry date | Age (years) | Gender | Medicines reported as being taken | MedDRA reaction terms |
| 570805 | 18/06/2021 | 59 | Male | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Deep vein thrombosis Pulmonary embolism |

we know this is the case that had a death reported also as we can filter for age and gender and also other reactions that had a death associated (deep vein thrombosis)

■ <u>5 medicines selected</u> between 21/06/2021 - 21/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

| Medicine summa | <u>ry</u> <u>List of reports</u> | | | |
|---------------------------------|--|---------------------|--|--|
| Medicine summ | ary | | | |
| The medicine summa | ary groups reported adverse ev | ents together. Pati | ients may have re | ported multiple |
| Further information | about the medicine summary | | | |
| Information on print | ng search results | | | |
| Sort by: | | | | rsion of this |
| Number of cases - h | ighest first | | report | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
| Vascular disorders | Peripheral ischaemia | 1 | 1 | 1 |

Verifiable death – Male –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 572390 | 21/06/2021 | - | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Mesenteric artery thrombosis Peripheral ischaemia |

■ <u>5 medicines selected</u> between 21/06/2021 - 21/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summa | List of reports | | | | | | | | |
|---------------------------------|---|--------------------|--|--|--|--|--|--|--|
| Medicine summary | | | | | | | | | |
| The medicine summa | ary groups reported adverse e | vents together. Pa | tients may have re | ported multiple | | | | | |
| Further information | about the medicine summary | | | | | | | | |
| Information on print | ing search results | | | | | | | | |
| Sort by: | | | | | | | | | |
| Number of cases - h | nighest first | | report | | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | | |
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 | | | | | |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 571893 | 21/06/2021 | 32 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Cardiac arrest Pulmonary embolism |

■ <u>5 medicines selected</u> between 21/06/2021 - 21/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|----------------------------------|--|--------------------|--|--|
| Injury, poisoning and procedural | Adverse event following immunisation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 571916 | 21/06/2021 | 46 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

■ 5 medicines selected between 22/06/2021 - 22/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

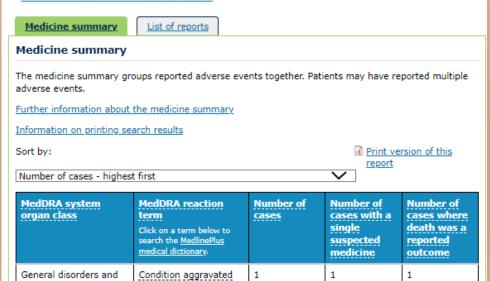
Number of reports (cases): 1

administration site

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: ${f 1}$

More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 572797 | 22/06/2021 | 70 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Condition aggravated Immune thrombocytopenia Platelet count abnormal |

■ <u>5 medicines selected</u> between 22/06/2021 - 22/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

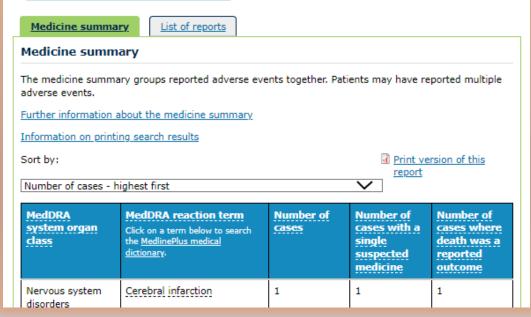
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 573003 | 22/06/2021 | 93 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | • <u>Cerebral</u> <u>infarction</u> |

■ 5 medicines selected between 22/06/2021 - 22/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 572757 | 22/06/2021 | 69 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Cardiac arrest Chest pain |

■ <u>5 medicines selected</u> between 22/06/2021 - 22/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summa | List of reports | | | | | | | |
|------------------------------------|---|-----------------|--|--|--|--|--|--|
| Medicine summary | | | | | | | | |
| The medicine summa adverse events. | | | | | | | | |
| Information on printi | | | | | | | | |
| Sort by: | Sort by: @ Print version of this report | | | | | | | |
| Number of cases - h | ighest first | | ~ | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | |
| Vascular disorders | Aortic aneurysm rupture | 1 | 1 | 1 | | | | |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 572665 | 22/06/2021 | 94 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Aortic aneurysm rupture |

■ 5 medicines selected between 23/06/2021 - 23/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single <u>suspected</u> medicine: 1

Number of cases where <u>death</u> was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 573150 | 23/06/2021 | 93 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebrovascular accident |

■ <u>5 medicines selected</u> between 23/06/2021 - 23/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

<u>Medicine summary</u>

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | |
|---|--|-----------------|--|--|--|
| General disorders and administration site | Multiple organ dysfunction syndrome | 1 | 1 | 1 | |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 573810 | 23/06/2021 | 63 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Altered state of consciousness Hepatic failure Multiple organ dysfunction syndrome Oedema peripheral Pain in extremity Pruritus |

■ 5 medicines selected between 24/06/2021 - 24/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 2

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|----------------------------------|--|-----------------|--|--|
| Injury, poisoning and procedural | Adverse event following immunisation | 2 | 1 | 2 |

1 - Verifiable death -Male -age 74

1 - Verifiable death -Male -age 82

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 574393 | 24/06/2021 | 74 | М | Tradename not specified (Product not coded) - Suspected COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |
| 575009 | 24/06/2021 | 82 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation Concomitant disease aggravated |

■ <u>5 medicines selected</u> between 24/06/2021 - 24/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Sort by: Print version of this report Number of cases - highest first ~ MedDRA system MedDRA reaction term Number of **Number of** Number of organ class cases with a cases where Click on a term below to search the MedlinePlus medical death was a single dictionary. suspected reported medicine outcome Platelet count decreased Investigations

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 573987 | 24/06/2021 | 86 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Clexane (Enoxaparin) Not suspected | Bradycardia Cerebrovascular accident Deep vein thrombosis Dysphagia Epistaxis Haematemesis Myocardial infarction Platelet count decreased Pulmonary embolism Splenic infarction Staphylococcal bacteraemia Vertigo |

■ <u>5 medicines selected</u> between 24/06/2021 - 24/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Vascular disorders | Cyanosis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 574229 | 24/06/2021 | 88 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Cyanosis Dyspnoea |

■ <u>5 medicines selected</u> between 25/06/2021 - 25/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

Gastrointestinal

disorders

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

Haematemesis

More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report Number of cases - highest first ~ MedDRA reaction term MedDRA system **Number of** Number of **Number of** cases with a organ class cases where cases Click on a term below to search the MedlinePlus medical single death was a dictionary. reported suspected medicine outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|-------------------------|--------------|--------|--|--|
| 575228 | 25/06/2021 | 61 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Tradename not specified (aspirin) - Not suspected APO-Metformin (metformin hydrochloride) - Not suspected APO-Telmisartan (hydrochlorothiazide; telmisartan) - Not suspected Apotex Rosuvastatin (rosuvastatin calcium) - Not suspected FluQuadri Vaccine (Influenza virus haemagglutinin) - Not suspected | Blood blister Cerebral haemorrhage Epistaxis Haematemesis Headache Immune thrombocytopenia Petechiae Rhinitis Somnolence Thrombocytopenia Vomiting |

■ 5 medicines selected between 25/06/2021 - 25/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

 $\underline{\mathsf{Medicine}\;\mathsf{summary}}$

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

~

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|----------------------------------|--|-----------------|--|--|
| Injury, poisoning and procedural | Adverse event following immunisation | 1 | 1 | 1 |

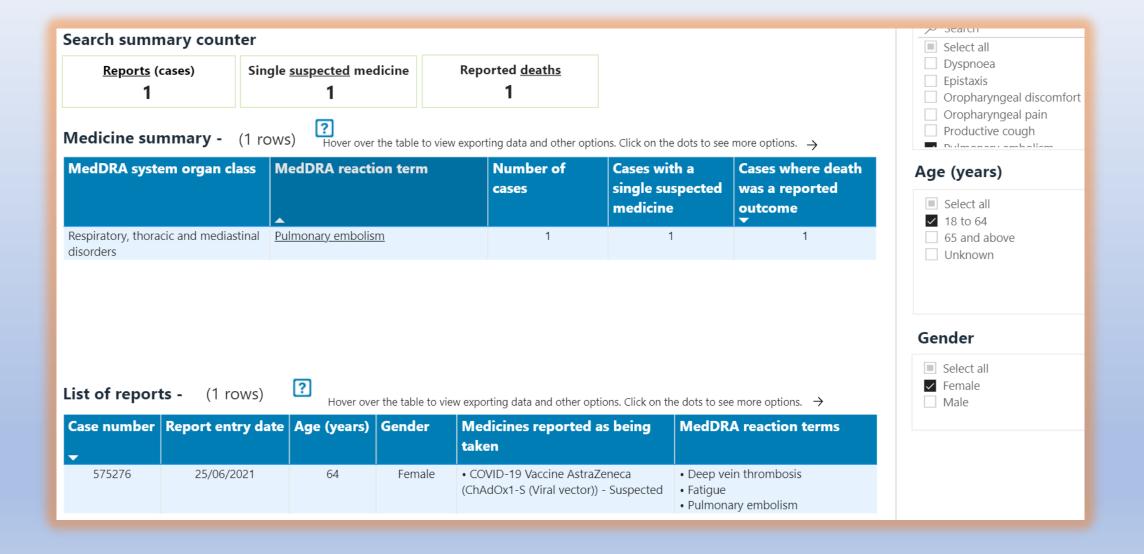
Verifiable death – Male – age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 575293 | 25/06/2021 | - | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

Verifiable death -Male -age 84

| Search summ | ary counter | | | | | | Select all | |
|--|---|--|--------------------|---|--|--|--|--|
| Reports (co 3 Medicine sum | | ngle <u>suspected</u> med 3 rows) Pover over | | orted <u>deaths</u> 1 ing data and other optic | ons. Click on the dots to see | e more options. → | Asthenia Chest discomfort ✓ Chest pain Chills Concomitant disease aggravated | |
| MedDRA system | m organ class | MedDRA reaction | on term | Number of cases | Cases with a single suspected medicine | Cases where death was a reported outcome | Age (years) Select all 65 and above | |
| General disorders a site conditions | General disorders and administration Chest pain 3 3 1 | | | | | | | |
| | | | | | | | Gender | |
| List of reports | List of reports - (3 rows) Select all | | | | | | | |
| Case number ▼ | Report entry o | date Age (years) | Gender Med take | dicines reported a en | s being MedDR | A reaction terms | | |
| 575493 | 25/06/2021 | 84 | | VID-19 Vaccine AstraZ dOx1-S (Viral vector)) | | ain | | |

We know this case had a death reported also as we can filter for gender and other cases that reported other reactions did not have a death reported also



Verifiable death –Female –age 64

| Search sumn | nary counter | | | | | | Select all |
|---------------------------------|----------------------|---------------------------|-----------------------|--|--|--|--|
| Reports (| cases) Si | ngle <u>suspected</u> med | 5 1 | | | | ☐ Cough☑ Dyspnoea☐ Epistaxis☐ Pneumonitis |
| Medicine sur | mmary - (1 r | OWS) Rover over | the table to view ex | porting data and other optic | ons. Click on the dots to see | more options. \rightarrow | Pulmonary embolism |
| MedDRA syste | em organ class | MedDRA reacti | on term | Number of cases | Cases with a single suspected medicine | Cases where death was a reported outcome | Age (years) Select all 18 to 64 |
| Respiratory, thora disorders | cic and mediastinal | <u>Dyspnoea</u> | | 6 | 6 | 1 | 65 and above |
| | | | | | | | Gender |
| List of report | ts - (6 rows) |) Plover ove | r the table to view e | exporting data and other opti | ons. Click on the dots to se | e more options. → | Select allFemaleMale |
| Case number ▼ | Report entry d | late Age (years) | | Medicines reported a aken | s being MedDR | A reaction terms | ^ |
| 575406 | 25/06/2021 | 74 | | COVID-19 Vaccine AstraZ ChAdOx1-S (Viral vector)) | - / - - · · - | ea | |

we know this case had a death reported also as the other cases all had other reactions not associated with a death

■ 5 medicines selected between 26/06/2021 - 26/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

<u>Medicine summary</u>

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 575852 | 26/06/2021 | 50 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardiac arrest Fibrin D dimer increased Infarction Pain in extremity Platelet count decreased Pulmonary embolism |

■ <u>5 medicines selected</u> between 27/06/2021 - 27/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Blood and lymphatic system disorders | Splenic thrombosis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 575973 | 27/06/2021 | 59 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Tradename not specified (paroxetine) - Not suspected Tradename not specified (tibolone) - Not suspected | Abdominal pain Chest pain Fibrin D dimer increased Infarction Nausea Portal vein thrombosis Pulmonary embolism Splenic thrombosis Thrombocytopenia Visceral venous thrombosis |

■ 5 medicines selected between 27/06/2021 - 27/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 2 | 2 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 576017 | 27/06/2021 | 62 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebrovascular accident |

■ 5 medicines selected between 28/06/2021 - 28/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

 $\overline{}$

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 576409 | 28/06/2021 | 79 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 28/06/2021 - 28/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Cardiac disorders

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

Myocardial infarction

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 576410 | 28/06/2021 | 79 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Coronary artery thrombosis Myocardial infarction Nasopharyngitis |

■ <u>5 medicines selected</u> between 28/06/2021 - 28/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|---|-----------------|--|--|
| General disorders and administration site conditions | Multiple organ dysfunction syndrome | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 576368 | 28/06/2021 | 76 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardiac arrest Multiple organ dysfunction syndrome |

■ 5 medicines selected between 28/06/2021 - 28/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 5

Respiratory, thoracic

and mediastinal disorders

Number of cases with a single suspected medicine: 4

Number of cases where death was a reported outcome: 1

medical dictionary.

Pulmonary embolism

More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report $\overline{}$ Number of cases - highest first MedDRA system MedDRA reaction **Number of** Number of **Number of** cases with a organ class term cases cases where single death was a Click on a term below to search the MedlinePlus suspected

reported

outcome

medicine

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 576408 | 28/06/2021 | 80 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Deep vein thrombosis Malaise Pulmonary embolism |

■ <u>5 medicines selected</u> between 29/06/2021 - 29/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Myocardial infarction | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 577133 | 29/06/2021 | 91 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Myocardial infarction |

■ <u>5 medicines selected</u> between 29/06/2021 - 29/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this <u>report</u>

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Gastrointestinal disorders | Intestinal ischaemia | 1 | 1 | 1 |

Verifiable death -Male -age 94

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 577131 | 29/06/2021 | 94 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Intestinal ischaemia Platelet count decreased |

■ 5 medicines selected between 29/06/2021 - 29/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 577072 | 29/06/2021 | 64 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebrovascular accident Deep vein thrombosis Ischaemic stroke |

■ <u>5 medicines selected</u> between 29/06/2021 - 29/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Vascular disorders

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

Thrombosis

More information on the search results

List of reports Medicine summary Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report Number of cases - highest first $\overline{}$ **MedDRA Number of Number of** Number of MedDRA reaction term cases with a cases where system organ cases Click on a term below to search class the MedlinePlus medical single death was a dictionary. suspected reported

medicine

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 576749 | 29/06/2021 | 86 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | AphasiaConfusional stateMuscular weaknessThrombosis |

■ 1 medicine selected between 29/06/2021 - 29/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 576744 | 29/06/2021 | 81 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Cardiac arrest Dyspnoea |

■ 5 medicines selected between 30/06/2021 - 30/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 3

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 3 | 3 | 3 |

- 1- Verifiable death -? -age 84
- 2- Verifiable death -Female -age 56
- 3- Verifiable death -Female -age 68

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 577430 | 30/06/2021 | 84 | - | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation Chills Cough Insomnia Vomiting |
| 577432 | 30/06/2021 | 56 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation Blood glucose decreased |
| 577489 | 30/06/2021 | 68 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation Diarrhoea Malaise |

■ <u>5 medicines selected</u> between 30/06/2021 - 30/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary Medicine summary

List of reports

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Gastrointestinal disorders | Intestinal ischaemia | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 577565 | 30/06/2021 | 78 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Intestinal ischaemia Septic shock |

■ <u>5 medicines selected</u> between 30/06/2021 - 30/06/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Intraventricular haemorrhage | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 577528 | 30/06/2021 | 62 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Intraventricular haemorrhage |

■ 5 medicines selected between 01/07/2021 - 01/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|-----------------------------|---|-----------------|--|--|
| Infections and infestations | Breast abscess | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 577898 | 01/07/2021 | 78 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Acute kidney injury Breast abscess Influenza like illness Pyrexia |

■ <u>5 medicines selected</u> between 01/07/2021 - 01/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

General disorders and

administration site

conditions

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



medical dictionary.

Multiple organ

dysfunction syndrome

suspected

medicine

reported

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 577930 | 01/07/2021 | 90 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cholecystitis acute Infection Multiple organ dysfunction syndrome Septic shock |

■ <u>5 medicines selected</u> between 01/07/2021 - 01/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: ${f 1}$

More information on the search results

| Medicine summary | <u>List of reports</u> | | | | | | | | | |
|--|------------------------|---------------------------------|------------------------------|--|--|--|--|--|--|--|
| Medicine summary | | | | | | | | | | |
| The medicine summary gro adverse events. | ups reported adve | rse events together. Patients n | nay have reported multiple | | | | | | | |
| Further information about the medicine summary | | | | | | | | | | |
| Information on printing sea | rch results | | | | | | | | | |
| Sort by: | | | Print version of this report | | | | | | | |
| Number of cases - highest | first | ~ | | | | | | | | |

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 2 | 2 | 1 |

Verifiable death –Female –age 86

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 578048 | 01/07/2021 | 86 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebrovascular accident |

We know this report had a death associated too as the other case also reported thrombosis which did not have a death associated with it

■ 5 medicines selected between 02/07/2021 - 02/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Vascular disorders | Hypotension | 1 | 0 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 579162 | 02/07/2021 | 70 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Warfarin (warfarin sodium) - Suspected | Abdominal pain upper Atrial fibrillation Epistaxis Heart rate increased Hypotension International normalised ratio increased Subdural haematoma |

■ <u>5 medicines selected</u> between 02/07/2021 - 02/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------------|--|-----------------|--|--|
| Metabolism and nutrition disorders | Hypophagia | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 579121 | 02/07/2021 | 94 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Delirium Dyspnoea Fatigue Hypophagia Parainfluenzae virus infection Pyrexia Tachycardia |

■ <u>5 medicines selected</u> between 04/07/2021 - 04/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

Investigations

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

Drug level increased

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 579573 | 04/07/2021 | 75 | F | Clozaril (clozapine) - Suspected COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Drug level increased Troponin increased |

■ <u>5 medicines selected</u> between 05/07/2021 - 05/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Eye disorders | Blindness unilateral | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 580051 | 05/07/2021 | 72 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Blindness unilateral Blood fibrinogen decreased Cerebral venous sinus thrombosis Fibrin D dimer increased Haemorrhage intracranial Headache Nausea Thrombosytopenia Thrombosytopenia syndrome Vomiting |

■ <u>5 medicines selected</u> between 06/07/2021 - 06/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

Nervous system disorders

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summai | | | | | | | |
|---|-----------|---|-------------|-----------------|---|---|--|
| Medicine summa | ary | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | |
| Further information a | about the | e medicine sumn | <u>nary</u> | | | | |
| Information on printi | ng searc | ch results | | | | | |
| Sort by: | | | | | | ersion of this | |
| Number of cases - highest first | | | | | | | |
| MedDRA system organ class | Click on | RA reaction tern a term below to se llinePlus medical ary. | | Number of cases | Number of cases with a single suspected | Number of cases where death was a reported | |

Ruptured cerebral aneurysm

medicine

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 580759 | 06/07/2021 | 58 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Back pain Headache Ruptured cerebral aneurysm Subarachnoid haemorrhage |

■ <u>5 medicines selected</u> between 07/07/2021 - 07/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary Medicine summary

List of reports

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Pericardial haemorrhage | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 581407 | 07/07/2021 | 79 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease progression Pericardial haemorrhage |

■ <u>5 medicines selected</u> between 07/07/2021 - 07/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: $\boldsymbol{0}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 0 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 581289 | 07/07/2021 | 73 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected FLUAD QUAD (Influenza virus haemagglutinin) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 07/07/2021 - 07/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Cognitive disorder | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 581649 | 07/07/2021 | 60 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cognitive disorder Concomitant disease aggravated Decreased appetite Lethargy |

■ 5 medicines selected between 07/07/2021 - 07/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 2

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|---|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 3 | 3 | 2 |

Verifiable death –Female –age 87

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 581533 | 07/07/2021 | 87 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected Tradename not specified (budesonide) - Not suspected Tradename not specified (Clotrimazole) - Not suspected Diamox (acetazolamide) - Not suspected Escitalopram AN (Escitalopram) - Not suspected Rabeprazole (rabeprazole sodium) - Not suspected | Concomitant disease progression |

we know this was 1 of the 2 deaths with this ailment as the 3rd had other reactions not associated with a death

■ 5 medicines selected between 08/07/2021 - 08/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Injury, poisoning and

procedural complications

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

medical dictionary.

Adverse event following immunisation

■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report Number of cases - highest first \sim **Number of** MedDRA system MedDRA reaction Number of **Number of** organ class term cases cases with a cases where death was a single Click on a term below to search the MedlinePlus suspected reported

medicine

outcome

1- Verifiable death –Male –age 822- Verifiable death –Female –age 73

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 582521 | 08/07/2021 | 82 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Adverse event following immunisation Vaccination error |
| 582827 | 08/07/2021 | 73 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 08/07/2021 - 08/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | |
|--|--|-----------------|--|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 1 | 1 | |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 582443 | 08/07/2021 | 62 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease progression Vaccination error |

■ <u>5 medicines selected</u> between 09/07/2021 - 09/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 583035 | 09/07/2021 | 67 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 09/07/2021 - 09/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

Metabolism and

nutrition disorders

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

Fluid intake reduced

dictionary.

■ More information on the search results

List of seconds

| Medicine summar | <u>List</u> | of reports | | | | | | |
|---|---------------------|--|---|-----------------|-------------------------------|---|--|--|
| Medicine summary | | | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | | |
| Further information at | bout the me | dicine summar | Y | | | | | |
| Information on printin | <u>ig search re</u> | <u>sults</u> | | | | | | |
| Sort by: | | | | | | rsion of this | | |
| Number of cases - high | ghest first | | | | report | | | |
| MedDRA system organ class | | reaction term erm below to sear Plus medical | | Number of cases | Number of cases with a single | Number of cases where death was a | | |

suspected

medicine

reported

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 583089 | 09/07/2021 | 85 | F | Cardizem (diltiazem hydrochloride) - Suspected COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Lasix (furosemide (frusemide)) - Suspected Spiractin (spironolactone) - Suspected Tradename not specified (Product not coded) - Interaction Tradename not specified (Product not coded) - Not suspected | Concomitant disease progression Fatigue Fluid intake reduced Pneumonia |

■ 1 medicine selected between 09/07/2021 - 09/07/2021.

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

General disorders and

administration site

conditions

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

■ More information on the search results

List of reports Medicine summary Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report Number of cases - highest first $\overline{}$ MedDRA reaction **Number of Number of** MedDRA system **Number of** organ class term cases cases with a cases where

Click on a term below to search the MedlinePlus

Concomitant disease

medical dictionary.

progression

death was a

reported

outcome

single

suspected

medicine

1 – Verifiable death – Female – age 82 2- Verifiable death Female –age 57

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 582846 | 09/07/2021 | 82 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Concomitant disease progression |
| 582919 | 09/07/2021 | 57 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected Crestor (rosuvastatin calcium) - Not suspected Eutroxsig (levothyroxine sodium) - Not suspected | Concomitant disease progression Paraesthesia |

1 – Verifiable death – Female – age 752- Verifiable death Female – age 94

| Search summary count | ter | | | | /- Scarcii | | | | |
|-----------------------------|----------------------------------|------------------------|---------------------------|------------------------|------------------------------|--|--|--|--|
| Search sammary count | Scarcii Saininal y Counter | | | | | | | | |
| Reports (cases) | Single <u>suspected</u> medicine | Reported deaths | | | Herpes zoster | | | | |
| <u>reports</u> (cases) | omgre <u>suspecteu</u> meureme | neported <u>deaths</u> | | | ✓ Pneumonia | | | | |
| 3 | 3 2 3 | | | | | | | | |
| | | | | | ☐ Urinary tract infection | | | | |
| Medicine summary - | | | | | | | | | |
| MedDRA system organ cla | Age (years) | | | | | | | | |
| | | cases | single suspected medicine | was a reported outcome | ■ Select all ✓ 65 and above | | | | |
| Infections and infestations | <u>Pneumonia</u> | 3 | 2 | 3 | Unknown | | | | |
| | | | | | | | | | |

| List of reports - (3 rows) Hover over the table to view exporting data and other options. Click on the dots to see more options. | | | | | |
|--|-------------------|-------------|--------|---|-----------------------|
| Case number ▼ | Report entry date | Age (years) | Gender | Medicines reported as being taken | MedDRA reaction terms |
| 583164 | 9/07/2021 | 75 | Female | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Micardis (telmisartan) - Not suspected Relpax (eletriptan hydrobromide) - Not suspected Tramadol (tramadol hydrochloride) - Not suspected Valium (diazepam) - Not suspected Ventolin (salbutamol) - Not suspected | Fatigue Pneumonia |
| 583020 | 9/07/2021 | 94 | Female | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | • Pneumonia |

■ <u>5 medicines selected</u> between 11/07/2021 - 11/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Ischaemic stroke | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 583670 | 11/07/2021 | 85 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Ischaemic stroke Pneumonia aspiration |

■ 5 medicines selected between 11/07/2021 - 11/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

More information on the search results

| Medicine summary | <u>List of reports</u> |
|------------------|------------------------|
| Medicine summary | |

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Somnolence | 1 | 1 | 1 |

Verifiable death – Female – age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 583673 | 11/07/2021 | - | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Coma scale abnormal Oxygen saturation Somnolence |

■ 5 medicines selected between 12/07/2021 - 12/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single $\underline{\text{suspected}}$ medicine: $\mathbf{1}$

Number of cases where death was a reported outcome: ${f 1}$

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Arteriosclerosis coronary artery | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 583922 | 12/07/2021 | 59 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Arteriosclerosis coronary artery |

■ 5 medicines selected between 12/07/2021 - 12/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summary | | <u>List of reports</u> |
|------------------|--|------------------------|
|------------------|--|------------------------|

Medicine summary

Sort by:

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Throwndaton on princing occircul results

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Coronary artery disease | 1 | 1 | 1 |

Print version of this

Verifiable death –Male –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 583871 | 12/07/2021 | - | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Coronary artery diseasePallorPeripheral swelling |

■ 1 medicine selected between 12/07/2021 - 12/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summary | | <u>List of reports</u> |
|------------------|--|------------------------|
|------------------|--|------------------------|

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

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| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 583981 | 12/07/2021 | 62 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease progression |

■ 5 medicines selected between 13/07/2021 - 13/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 4

Number of cases with a single suspected medicine: 4

Number of cases where death was a reported outcome: 4

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|---|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 4 | 4 | 4 |

- 1 Verifiable death -Female -age 85
- 2 Verifiable death –Female –age 65
 - 3 Verifiable death -Male -age 49
 - 4 Verifiable death -Male -age 86

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 584822 | 13/07/2021 | 85 | F | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | Adverse event following immunisation |
| 584827 | 13/07/2021 | 65 | F | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | Adverse event following immunisation |
| 584829 | 13/07/2021 | 49 | М | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | Adverse event following immunisation Myalgia Presyncope |
| 585154 | 13/07/2021 | 86 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 13/07/2021 - 13/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

More information on the search results

| Medicine summa | List of reports | | | |
|-----------------------------------|---|---------------------|--|--|
| Medicine sumn | nary | | | |
| The medicine summ adverse events. | nary groups reported adverse ev | ents together. Pati | ients may have re | ported multiple |
| Further information | about the medicine summary | | | |
| Information on print | ting search results | | | |
| Sort by: | | | | rsion of this |
| Number of cases - | highest first | | report | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
| Eye disorders | Eye haemorrhage | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 585166 | 13/07/2021 | 97 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Acute myocardial infarction Eye haemorrhage Fibrin D dimer increased Immune thrombocytopenia Subdural haemorrhage |

■ 5 medicines selected between 13/07/2021 - 13/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

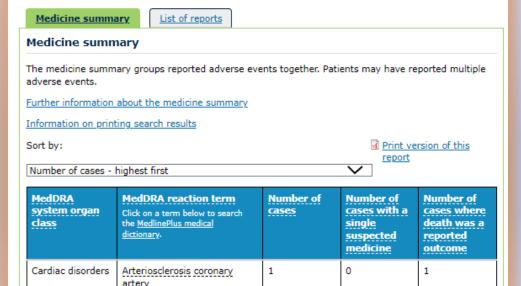
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 585324 | 13/07/2021 | 66 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected FLUAD QUAD (Influenza virus haemagglutinin) - Suspected | Arteriosclerosis coronary artery |

■ <u>5 medicines selected</u> between 13/07/2021 - 13/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Cerebral venous sinus thrombosis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 585318 | 13/07/2021 | 48 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebral haemorrhage Cerebral venous sinus thrombosis Fibrin D dimer increased Headache Herpes zoster Thrombocytopenia Thrombosis with thrombocytopenia syndrome |

■ 5 medicines selected between 13/07/2021 - 13/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

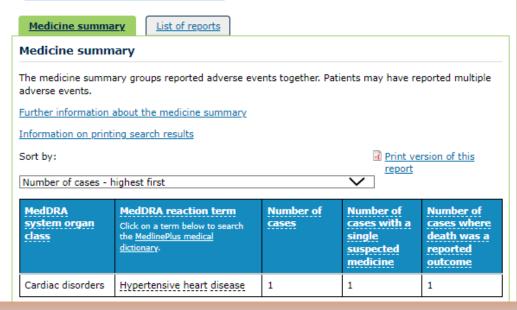
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 584834 | 13/07/2021 | 71 | М | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | Hypertensive heart disease Ischaemia |

■ <u>5 medicines selected</u> between 13/07/2021 - 13/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single $\underline{\text{suspected}}$ medicine: $\boldsymbol{1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Immune system disorders | Seasonal allergy | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 584645 | 13/07/2021 | 66 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease progression Seasonal allergy |

■ <u>5 medicines selected</u> between 14/07/2021 - 14/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

Infections and

infestations

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

dictionary.

Pneumonia

■ More information on the search results

| Medicine summar | <u>List of reports</u> | | | | | | |
|---|--|-----------------|-------------------------------|---|--|--|--|
| Medicine summary | | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | |
| Further information al | bout the medicine summary | | | | | | |
| Information on printin | g search results | | | | | | |
| Sort by: | | | Print ve | rsion of this | | | |
| Number of cases - highest first | | | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical | Number of cases | Number of cases with a single | Number of cases where death was a | | | |

reported

outcome

suspected

medicine

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 585806 | 14/07/2021 | 90 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | AstheniaConcomitant disease aggravatedPneumonia |

■ <u>5 medicines selected</u> between 14/07/2021 - 14/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Coronary artery disease | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 585735 | 14/07/2021 | 68 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Coronary artery disease |

■ <u>5 medicines selected</u> between 14/07/2021 - 14/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|---|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 585981 | 14/07/2021 | 81 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

■ 5 medicines selected between 14/07/2021 - 14/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 2 | 2 | 1 |

Verifiable death –Male –age 58

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 585942 | 14/07/2021 | 58 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebrovascular accident Fibrin D dimer |

we know this is the one that resulted in death as it also had another reaction that was associated with a death (fibrin d dimer)

■ 5 medicines selected between 15/07/2021 - 15/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Haemorrhage intracranial | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 586554 | 15/07/2021 | 44 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Fibrin D dimer increased Haemorrhage intracranial Hepatic infarction Intestinal infarction Pulmonary embolism Splenic infarction Thrombocytopenia Thrombosis with thrombocytopenia syndrome |

■ 5 medicines selected between 15/07/2021 - 15/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

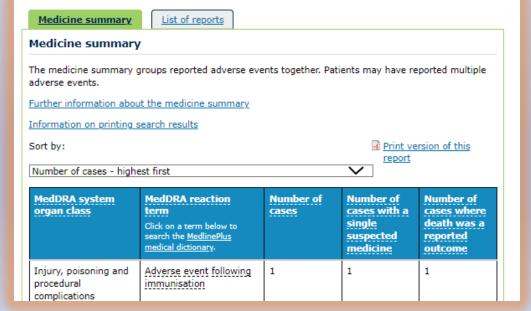
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 587068 | 15/07/2021 | 66 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

Verifiable death –Female –age 51

| Reports (cases) | ☐ Herpes zoster☐ Malassezia infection☑ Nasopharyngitis☐ Oral herpes | | | | | | |
|--|--|---|---|---|---------------------------|--|--|
| Medicine summary - | Pneumonia Urinary tract infection | | | | | | |
| MedDRA system organ class MedDRA reaction term MedDRA reaction term Number of cases with a single suspected was a reported MedDRA reported | | | | | | | |
| medicine outcome | | | | | | | |
| Infections and infestations | <u>Nasopharyngitis</u> | 3 | 3 | 1 | ✓ 18 to 64 ☐ 65 and above | | |

| Case number ▼ | Report entry date | Age (years) | Gender | Medicines reported as being taken | MedDRA reaction terms |
|----------------|-------------------|-------------|--------|--|-------------------------------|
| 586848 | 15/07/2021 | 43 | Female | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Nasopharyngitis Pneumonia |
| 586817 | 15/07/2021 | 31 | Female | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Asthma Nasopharyngitis |
| 586732 | 15/07/2021 | 51 | Female | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Nasopharyngitis |

we know this case had a death reported also. The others can be excluded as their other symptoms were not associated with a death.

■ 5 medicines selected between 16/07/2021 - 16/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|---|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 587237 | 16/07/2021 | 43 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 16/07/2021 - 16/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Number of cases - highest first

Sort by:

Print version of this report

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 587205 | 16/07/2021 | 81 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Aortic aneurysm rupture Cardiac arrest Gastrooesophageal reflux disease Headache Malaise |

■ <u>5 medicines selected</u> between 16/07/2021 - 16/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Acute disseminated encephalomyelitis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 587654 | 16/07/2021 | 72 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Acute disseminated encephalomyelitis Guillain-Barre syndrome Respiratory failure |

■ <u>5 medicines selected</u> between 18/07/2021 - 18/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Coronary artery disease | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 588021 | 18/07/2021 | 75 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected FLUAD QUAD (Influenza virus haemagglutinin) - Not suspected | Coronary artery disease |

■ <u>5 medicines selected</u> between 20/07/2021 - 20/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Cardiac disorders

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

Cardiac failure

■ More information on the search results

| Medicine summa | List of reports | | | | | | | |
|-----------------------------------|---|-----------------|--|--|--|--|--|--|
| Medicine summary | | | | | | | | |
| The medicine summ adverse events. | The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | |
| Further information | about the medicine summary | | | | | | | |
| Information on print | ing search results | | | | | | | |
| Sort by: | | | | rsion of this | | | | |
| Number of cases - I | highest first | | report | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 588770 | 20/07/2021 | 91 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardiac failure Epistaxis Fibrin D dimer increased Immune thrombocytopenia |

■ 1 medicine selected between 20/07/2021 - 20/07/2021.

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Infections and infestations | Herpes zoster | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 588772 | 20/07/2021 | 90 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cerebrovascular accident Herpes zoster |

■ 5 medicines selected between 21/07/2021 - 21/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

Verifiable death –Male –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 589841 | 21/07/2021 | - | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Acute kidney injury Adverse event following immunisation Anaemia Back pain Deep vein thrombosis Metastases to liver Pulmonary embolism |

■ <u>5 medicines selected</u> between 21/07/2021 - 21/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

| Med | licine | summa | <u>ry</u> | Li |
|-----|--------|-------|-----------|----|
| | | | | |

<u>List of reports</u>

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Brain stem haemorrhage | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 589650 | 21/07/2021 | 76 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Tradename not specified (Product not coded) - Not suspected Eliquis (apixaban) - Not suspected Metoprolol (metoprolol tartrate) - Not suspected Rosuvastatin (rosuvastatin calcium) - Not suspected Zostavax (live varicella vaccine) - Not suspected | Brain stem haemorrhage |

■ 5 medicines selected between 22/07/2021 - 22/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single <u>suspected</u> medicine: 2

Number of cases where <u>death</u> was a reported outcome: 2

More information on the search results

| Medicine summa | List of reports | | | | | |
|---|--|-----------------|--|--|--|--|
| Medicine summary | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | |
| Further information | about the medicine summary | | | | | |
| Information on print | ing search results | | | | | |
| Sort by: | | | | rsion of this | | |
| Number of cases - h | nighest first | | report | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | |
| Cardiac disorders | Cardiac arrest | 2 | 2 | 2 | | |

1 - Verifiable death –Female –age 682 - Verifiable death –Male –age 60

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 590090 | 22/07/2021 | 68 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardiac arrest |
| 590714 | 22/07/2021 | 60 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardiac arrest Deep vein thrombosis Pulmonary embolism |

| Search summary coun | ter | | | | Select all |
|---|---------------------------------|--|---------------------------------|----------------------------------|---|
| Reports (cases) | Single <u>suspected</u> medicin | e Reported <u>deaths</u> 1 | | | ✓ Adverse event following immunisation ☐ Contusion ☐ Exposure via breast milk |
| Medicine summary - | (1 rows) Prover over the ta | able to view exporting data and other opti | ons. Click on the dots to see | more options. \rightarrow | ☐ Muscle strain ☐ Vaccination error |
| MedDRA system organ c | ass MedDRA reaction t | erm Number of cases | Cases with a single suspected | Cases where death was a reported | Age (years) |
| | | ▼ | medicine | outcome | ☐ Select all ☐ 18 to 64 |
| Injury, poisoning and procedura complications | Adverse event following | immunisation 1 | 1 | 1 | 10 to 04 |
| | | | | | |
| | | | | | |
| | | | | | Gender |
| List of reports - (1 rd | OWS) Plover over the | table to view exporting data and other op | tions. Click on the dots to see | e more options. 🔿 | ■ Select all ■ Female ■ Male |
| Case number Report ent | try date Age (years) Ge | nder Medicines reported taken | as being MedDR | A reaction terms | |
| 590275 22/07/2 | 021 62 F | emale • COVID-19 Vaccine Astraz | Zeneca • Adverse | event following | |

| Search summary | counter | | | | | | Burning feet syndrome |
|------------------------------------|----------------|--|------------------|--|-------------------------------|----------------------------------|---|
| Reports (cases) 1 Medicine summa | | suspected medic 1 S) Prover over the | | Reported <u>deaths</u> 1 xporting data and other opti | ons. Click on the dots to see | more options. \rightarrow | □ Burning sensation☑ Cerebrovascular accident□ Dizziness□ Dysgeusia□ Dyskinesia |
| MedDRA system or | gan class M | ledDRA reaction | | Number of cases | Cases with a single suspected | Cases where death was a reported | Age (years) |
| | | erebrovascular accide | | - | medicine | outcome | ☐ Select all ☐ 18 to 64 |
| | | | | | | | |
| | | | | | | | Gender |
| List of reports - | (1 rows) | ? Hover over th | ne table to view | exporting data and other opt | ions. Click on the dots to se | e more options. → | ■ Select all ▼ Female □ Male |
| Case number Repo | ort entry date | Age (years) G | | Medicines reported a taken | as being MedDR | A reaction terms ^ | |
| 590425 | 22/07/2021 | 61 | Female • | COVID-19 Vaccine Astraz | Zeneca • Cerebro | vascular accident | |

■ 5 medicines selected between 23/07/2021 - 23/07/2021.

Selected medicines

| Trade name | Active ingredients | | |
|------------------------------|---------------------------------------|--|--|
| COMIRNATY COVID-19 vaccine | tozinameran | | |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) | | |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) | | |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) | | |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) | | |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

<u>List of reports</u>

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | |
|---------------------------------|--|-----------------|--|--|--|
| Cardiac disorders | Myocardial infarction | 1 | 1 | 1 | |

Verifiable death -Male -age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 591215 | 23/07/2021 | - | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Myocardial infarction |

■ 5 medicines selected between 26/07/2021 - 26/07/2021.

Selected medicines

| Trade name | Active ingredients | | |
|------------------------------|---------------------------------------|--|--|
| COMIRNATY COVID-19 vaccine | tozinameran | | |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) | | |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) | | |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) | | |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) | | |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report Number of cases - highest first MedDRA Number of MedDRA reaction term **Number of Number of** cases where system organ cases with a cases Click on a term below to search class single death was a the MedlinePlus medical dictionary. suspected reported medicine outcome Cardiac arrest Cardiac disorders

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 592497 | 26/07/2021 | 80 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Abdominal pain Acute kidney injury Cardiac arrest Cardiogenic shock Decreased appetite Dizziness Fatigue Hypoxic-ischaemic encephalopathy Lymphoma Multiple organ dysfunction syndrome Nausea Upper gastrointestinal haemorrhage |

■ <u>5 medicines selected</u> between 27/07/2021 - 27/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

conditions

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together, Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report Number of cases - highest first $\overline{}$ MedDRA system MedDRA reaction **Number of** Number of Number of organ class cases with a cases where single death was a Click on a term below to search the MedlinePlus reported suspected medical dictionary. medicine outcome General disorders and Concomitant disease administration site progression

1 - Verifiable death -Female -age 81

2 - Verifiable death -Male -age 42

| | | | | | ropore |
|----------------|----------------------|--------------|--------|---|--|
| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
| 592782 | 27/07/2021 | 81 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease progression |
| 592806 | 27/07/2021 | 42 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Concomitant disease progression Cough Dyspnoea |

■ 5 medicines selected between 27/07/2021 - 27/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Musculoskeletal and connective tissue disorders | Musculoskeletal pain | 1 | 1 | 1 |

Verifiable death –Female –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 592707 | 27/07/2021 | - | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected FLUAD QUAD (Influenza virus haemagglutinin) - Not suspected | Cerebrovascular accident Deep vein thrombosis Electrocardiogram ST-T segment abnormal Fibrin D dimer increased Hyperhidrosis Musculoskeletal pain Presyncope Pulmonary embolism Troponin increased |

■ 1 medicine selected between 27/07/2021 - 27/07/2021.

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first



| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 593330 | 27/07/2021 | 64 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cerebrovascular accident |

■ 5 medicines selected between 28/07/2021 - 28/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 2 | 2 | 2 |

1- Verifiable death –Male –age 76

1- Verifiable death -Male -age 77

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 593550 | 28/07/2021 | 76 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |
| 593763 | 28/07/2021 | 77 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation Arthralgia Haematuria Myalgia |

■ <u>5 medicines selected</u> between 28/07/2021 - 28/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|---|--------------------|--|--|
| Hepatobiliary disorders | Hepatic failure | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 593820 | 28/07/2021 | 77 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease progression Fibrin D dimer increased Hepatic failure Thrombocytopenia |

■ 1 medicine selected between 28/07/2021 - 28/07/2021.

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 1 | 1 | 1 |

Verifiable death -age & sex undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 593828 | 28/07/2021 | - | - | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cerebrovascular accident |

■ <u>5 medicines selected</u> between 30/07/2021 - 30/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Cardiac disorders | Cardiac ventricular thrombosis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 595258 | 30/07/2021 | 78 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardiac ventricular thrombosis Cerebral infarction Fibrin D dimer increased Sepsis Thrombocytopenia |

■ 1 medicine selected between 30/07/2021 - 30/07/2021.

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | <u>Fall</u> | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 594970 | 30/07/2021 | 86 | М | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | • <u>Fall</u> |

■ 5 medicines selected between 30/07/2021 - 30/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Myocardial infarction | 2 | 2 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 595381 | 30/07/2021 | 91 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Myocardial infarction |

■ 1 medicine selected between 30/07/2021 - 30/07/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summary | <u>List of reports</u> |
|------------------|------------------------|
|------------------|------------------------|

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first



| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 595253 | 30/07/2021 | 92 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease progression |

■ <u>5 medicines selected</u> between 01/08/2021 - 01/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------|--|-----------------|--|--|
| Investigations | Coma scale abnormal | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 595824 | 01/08/2021 | 34 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebral venous sinus thrombosis Coma scale abnormal Fibrin D dimer increased Haemorrhagic transformation stroke Headache Intracranial pressure increased Neck pain Thrombocytopenia Thrombosis with thrombocytopenia syndrome |

■ <u>5 medicines selected</u> between 01/08/2021 - 01/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Infections and infestations | Pneumonia aspiration | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 595770 | 01/08/2021 | 50 | M | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cardiac arrest Headache Hypoxic-ischaemic encephalopathy Immune-mediated encephalitis Pneumonia aspiration Seizure Vomiting |

■ 5 medicines selected between 01/08/2021 - 01/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 595766 | 01/08/2021 | 87 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease progression |

■ <u>5 medicines selected</u> between 01/08/2021 - 01/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: ${f 1}$

List of reports

■ More information on the search results

Medicine summary Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| 5 y | edDRA stem organ ass | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------|----------------------------|---|-----------------|--|--|
| 1 | rvous system sorders | Cerebral haemorrhage | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 595661 | 01/08/2021 | 72 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebral haemorrhage Generalised tonic- clonic seizure Headache |

■ 5 medicines selected between 02/08/2021 - 02/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where <u>death</u> was a reported outcome: 1

■ More information on the search results

<u>Medicine summary</u>

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Myocardial ischaemia | 1 | 1 | 1 |

Verifiable death –Male –age undisclosed

Gender Medicines reported as Report Age **MedDRA reaction** Case number entry date (yrs) being taken terms Click on a term below to search the MedlinePlus medical dictionary. 02/08/2021 • COVID-19 Vaccine 595884 М Arteriosclerosis AstraZeneca coronary artery (ChAdOx1-S (Viral · Myocardial ischaemia vector)) - Suspected

■ 5 medicines selected between 02/08/2021 - 02/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Нурорпоеа | 1 | 0 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 596030 | 02/08/2021 | 71 | F | Tradename not specified (Product not coded) - Suspected COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | • <u>Hypopnoea</u> |

■ 5 medicines selected between 03/08/2021 - 03/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 3

More information on the search results

List of reports Medicine summary Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report $\overline{\mathsf{v}}$ Number of cases - highest first MedDRA system MedDRA reaction Number of Number of Number of organ class term cases cases with a cases where single death was a Click on a term below to search the MedlinePlus suspected reported medical dictionary. medicine outcome Injury, poisoning and Adverse event following procedural immunisation complications

- 1 Verifiable death -Male -age 80
- 1 Verifiable death -Male -age 76
- 1 Verifiable death -Male -age 50

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 596980 | 03/08/2021 | 80 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |
| 596981 | 03/08/2021 | 76 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Eliquis (apixaban) - Not suspected | Adverse event following immunisation Dyspnoea Infection Palpitations |
| 597267 | 03/08/2021 | 50 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation Syncope Thrombocytopenia |

■ <u>5 medicines selected</u> between 03/08/2021 - 03/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Pericardial haemorrhage | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 596900 | 03/08/2021 | 78 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Pericardial haemorrhage |

■ 5 medicines selected between 03/08/2021 - 03/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Number of cases - highest first

Print version of this report

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 1 | 1 |

Verifiable death –Female –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 596955 | 03/08/2021 | - | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease progression |

| Search summary cou | nter | | | | | Nasal congestion |
|-------------------------------|--------------------------------|-----------------------------|----------------------------|-------------------------------|----------------------------------|--|
| Reports (cases) | Single <u>suspected</u> m | nedicine Repo | orted <u>deaths</u> 1 | | | ☐ Oropharyngeal pain ☐ Pharyngeal swelling ☐ Pulmonary congestion ☑ Pulmonary embolism |
| Medicine summary - | (1 rows) Plover ov | ver the table to view expor | ting data and other optior | ns. Click on the dots to see | more options. \rightarrow | Rhinorrhoea |
| MedDRA system organ | class MedDRA read | tion term | Number of cases | Cases with a single suspected | Cases where death was a reported | Age (years) |
| | | | Cases | medicine | outcome | Select all 65 and above |
| Respiratory, thoracic and med | iastinal <u>Pulmonary embo</u> | <u>lism</u> | 1 | 1 | 1 | os and above |
| | | | | | | |
| | | | | | | |
| | | | | | | Gender |
| List of reports - (1 | rows) ? | over the table to view expo | rting data and other optic | ons. Click on the dots to see | e more options. → | ■ Select all □ Female ✓ Male |
| Case number Report e | ntry date Age (years | Gender Med take | dicines reported as en | s being MedDR | A reaction terms | |
| 596892 3/08 | /2021 65 | Male • CO | VID-19 Vaccine AstraZe | neca • Pulmona | ary embolism | |

■ 1 medicine selected between 04/08/2021 - 04/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

More information on the search results

| Medicine summary List of report |
|---------------------------------|
|---------------------------------|

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 2 | 2 | 1 |

Verifiable death –Male –age 80

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 597796 | 04/08/2021 | 80 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebrovascular accident |

we know this was the case that had a death reported also as the other case reported additional reactions that did not have a death associated with it

■ <u>5 medicines selected</u> between 05/08/2021 - 05/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

More information on the search results

| | Medicine summary | <u>List of reports</u> | | |
|---|---|------------------------|----------------------------------|---------------------------|
| | Medicine summary | | | |
| | The medicine summary gro adverse events. | ups reported adve | rse events together. Patients ma | ay have reported multiple |
| | Further information about t | he medicine summ | <u>nary</u> | |
| | Information on printing sea | rch results | | |
| | Sort by: | | [| Print version of this |
| | Number of cases - highest | first | | report |
| 1 | realitibes of educes inightese | moc | <u> </u> | |

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Myocardial fibrosis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 598170 | 05/08/2021 | 89 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Arteriosclerosis coronary artery Cardiomegaly Myocardial fibrosis |

■ 1 medicine selected between 05/08/2021 - 05/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single <u>suspected</u> medicine: 1

Number of cases where <u>death</u> was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Congestive cardiomyopathy | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 598238 | 05/08/2021 | 76 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Congestive cardiomyopathy |

1 - Verifiable death -Male -age 82

2 - Verifiable death -Male -age 86

| Search summary coun | ter | | | | | | MedDRA reactions (1 selected) Search Select all |
|---|-----|-----------------------------|------------------|-----------------|--|--|---|
| Reports (cases) 2 Single suspected medicine 2 Reported deaths 2 Medicine summary - (1 rows) Reported deaths 2 | | | | | | more options. → | ✓ Adverse event following immunisation ☐ Chillblains ☐ Concussion ☐ Product administered at inappropriate site ☐ Vaccination error |
| MedDRA system organ cl | ass | MedDRA reaction term | | Number of cases | Cases with a single suspected medicine | Cases where death was a reported outcome | Age (years) Select all 65 and above |
| Injury, poisoning and procedura | | Adverse event following imm | <u>unisation</u> | 2 | 2 | 2 | os and above |

| Case number ▼ | Report entry date | Age (years) | Gender | Medicines reported as being taken | MedDRA reaction terms |
|----------------------|-------------------|-------------|--------|---|--------------------------------------|
| 598472 | 5/08/2021 | 82 | Male | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |
| 598302 | 5/08/2021 | 86 | Male | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | Adverse event following immunisation |

■ 5 medicines selected between 06/08/2021 - 06/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 3

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 3 | 3 | 3 |

- 1 Verifiable death -Female -age 60
 - 2 Verifiable death -Male -age 50
- 3 Verifiable death –Female –age 87

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 598769 | 06/08/2021 | 60 | F | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | Adverse event following immunisation Diarrhoea Malaise Pyrexia Tachypnoea Vomiting |
| 598785 | 06/08/2021 | 50 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |
| 598895 | 06/08/2021 | 87 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 06/08/2021 - 06/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|---|-----------------|--|--|
| Infections and infestations | Sepsis | 2 | 2 | 2 |

1 - Verifiable death -Male -age 85

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 598846 | 06/08/2021 | 85 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cellulitis streptococcal Chills Pyrexia Sepsis |
| 598896 | 06/08/2021 | 90 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Fall Lower respiratory tract infection Oxygen saturation decreased Sepsis Syncope Vomiting |

■ 5 medicines selected between 06/08/2021 - 06/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary Medicine summary

List of reports

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac failure | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 598671 | 06/08/2021 | 77 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardiac arrest Cardiac failure Dyspnoea Emphysema Pulmonary fibrosis Pulmonary hypertension |

■ <u>5 medicines selected</u> between 06/08/2021 - 06/08/2021.

Selected medicines

| Trade name | Active ingredients | |
|------------------------------|---------------------------------------|--|
| COMIRNATY COVID-19 vaccine | tozinameran | |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) | |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) | |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) | |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) | |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|--------------------|--|--|
| Musculoskeletal and connective tissue disorders | Groin pain | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 598851 | 06/08/2021 | 52 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Chest pain Cough Dyspnoea Groin pain Malaise Myocardial infarction Myocarditis |

■ 5 medicines selected between 06/08/2021 - 06/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

administration site

conditions

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

deterioration

More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report Number of cases - highest first $\overline{}$ MedDRA system MedDRA reaction **Number of Number of Number of** organ class cases cases with a cases where term single death was a Click on a term below to search the MedlinePlus suspected reported medical dictionary. medicine outcome General physical health General disorders and

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 598893 | 06/08/2021 | 98 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Fall General physical health deterioration Lethargy Syncope |

■ <u>5 medicines selected</u> between 08/08/2021 - 08/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Seizure | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 599522 | 08/08/2021 | 73 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cognitive disorder Concomitant disease progression Deep vein thrombosis Fibrin D dimer increased Pulmonary embolism Seizure Subarachnoid haemorrhage Thrombocytopenia |

■ <u>5 medicines selected</u> between 09/08/2021 - 09/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 4

Number of cases with a single suspected medicine: 4

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summ | <u>List of reports</u> | | | | | | |
|----------------------------------|---|-----------------|--|--|--|--|--|
| Medicine sumn | Medicine summary | | | | | | |
| The medicine summadverse events. | The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | |
| Further information | about the medicine summary | | | | | | |
| Information on prin | ting search results | | | | | | |
| Sort by: | | | Print ve | rsion of this | | | |
| Number of cases - | highest first | | V | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | |
| Nervous system disorders | Cerebrovascular accident | 4 | 4 | 1 | | | |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 599727 | 09/08/2021 | 99 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebrovascular accident Fall |

■ <u>5 medicines selected</u> between 10/08/2021 - 10/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|-----------------------------|---|-----------------|--|--|
| Infections and infestations | Pneumonia aspiration | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 600986 | 10/08/2021 | 98 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Confusional state Disorientation Pneumonia |

■ <u>5 medicines selected</u> between 11/08/2021 - 11/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Cardiac disorders | Arrhythmia | 2 | 2 | 1 |

Verifiable death –Female –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 601767 | 11/08/2021 | - | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Arrhythmia Concomitant disease aggravated |

■ <u>5 medicines selected</u> between 11/08/2021 - 11/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single <u>suspected</u> medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Gastrointestinal disorders | Pancreatitis acute | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 601377 | 11/08/2021 | 76 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Dyspnoea Pancreatitis acute |

■ <u>5 medicines selected</u> between 12/08/2021 - 12/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first



| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Hypoxic-ischaemic encephalopathy | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 602379 | 12/08/2021 | 42 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Arthralgia Headache Hypoxic-ischaemic encephalopathy |

■ <u>5 medicines selected</u> between 12/08/2021 - 12/08/2021.

Selected medicines

| Trade name | Active ingredients | |
|------------------------------|---------------------------------------|--|
| COMIRNATY COVID-19 vaccine | tozinameran | |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) | |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) | |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) | |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) | |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Medicine summary

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 1

List of reports

More information on the search results

| Medicine summary | |
|--|------------------------------|
| The medicine summary groups reported adverse events together. Patients adverse events. | may have reported multipl |
| Further information about the medicine summary | |
| Information on printing search results | |
| Sort by: | Print version of this report |
| Number of cases - highest first | |

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Guillain-Barre syndrome | 3 | 3 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 602118 | 12/08/2021 | 77 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Guillain-Barre syndrome Nausea Pulmonary embolism |

- 1 Verifiable death -Female -age 81
- 2 Verifiable death -Female -age 70

Search summary counter

Reports (cases) Single suspected medicine

Reported <u>deaths</u>

2

Medicine summary - (1 rows)

Hover over the table to view exporting data and other options. Click on the dots to see more options. \rightarrow

| MedDRA system organ class | MedDRA reaction term | cases | Cases with a single suspected medicine | Cases where death was a reported outcome |
|--|--------------------------------------|-------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 2 | 2 | 2 |

List of reports - (2 rows)

?

Hover over the table to view exporting data and other options. Click on the dots to see more options. \rightarrow

| Case number ▼ | Report entry date | Age (years) | Gender | Medicines reported as being taken | MedDRA reaction terms |
|----------------------|-------------------|-------------|--------|--|--------------------------------------|
| 602916 | 13/08/2021 | 81 | Female | • COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |
| 602737 | 13/08/2021 | 70 | Female | COVID-19 Vaccine AstraZeneca | Adverse event following |

| > Search |
|--|
| Select all |
| ✓ Adverse event following immunisation |
| |
| ☐ Fall |
| ☐ Vaccination error |
| |
| |
| |
| |
| Age (years) |
| |
| Select all |
| ✓ 65 and above |
| <u> </u> |
| Unknown |
| |
| |
| |
| |
| |
| Gender |
| Gender |
| Select all |
| |
| Female |
| |
| |
| |
| |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Demyelination | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 602799 | 13/08/2021 | 73 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | AstheniaDemyelinationLethargyRespiratory disorder |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Cardiac disorders | Acute myocardial infarction | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 604158 | 16/08/2021 | 56 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Acute myocardial infarction Chills |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first



| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Infections and infestations | Pneumonia | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 603987 | 16/08/2021 | 60 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Deep vein thrombosis Pneumonia Pulmonary embolism |

| Search summary coun | ter | | | | Contusion | |
|--|----------------------------------|---|-------------------------------|-----------------------------|--|--|
| <u>Reports</u> (cases) | Single <u>suspected</u> medicine | Reported <u>deaths</u> | | | ☐ Fall ✓ Myocardial infarction ☐ Myocarditis | |
| Medicine summary - | (1 rows) Pover over the table | e to view exporting data and other optic | ons. Click on the dots to see | more options. \rightarrow | Palpitations Pericarditis | |
| MedDRA system organ cl | lass MedDRA reaction ter | | Cases with a | Cases where death | Age (years) | |
| | | cases | single suspected medicine | was a reported outcome | ☐ Select all ☐ 65 and above | |
| Cardiac disorders | Myocardial infarction | 1 | 1 | 1 | | |
| | | | | | Canadan | |
| | | | | | Gender | |
| List of reports - (1 rows) ☐ Select all Hover over the table to view exporting data and other options. Click on the dots to see more options. → Male | | | | | | |
| Case number Report ent | try date Age (years) Gend | er Medicines reported a taken | s being MedDR | A reaction terms | | |
| 603999 16/08/2 | 2021 80 Fer | • COVID-19 Vaccine AstraZ (ChAdOx1-S (Viral vector)) | _ | dial infarction | | |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Vascular disorders | Haemodynamic instability | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 605585 | 17/08/2021 | 73 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Anaemia Ascites C-reactive protein increased Deep vein thrombosis Fibrin D dimer increased Haemodynamic instability Pulmonary embolism Thrombocytopenia |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|-----------------------------|--|-----------------|--|--|
| Infections and infestations | Pneumonia | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 604900 | 17/08/2021 | 61 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Multiple organ dysfunction syndrome Pneumonia Septic shock |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summary | List of reports |
|------------------|-----------------|
| | |

Medicine summary

Sort by:

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

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Number of cases - highest first

Print version of this report

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Cerebrovascular disorder | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 605347 | 17/08/2021 | 86 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cerebrovascular accident Cerebrovascular disorder |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

<u>Medicine summary</u>

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Cerebral haemorrhage | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 605174 | 17/08/2021 | 89 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebral haemorrhage |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

procedural

complications

The results are shown in two tabs.

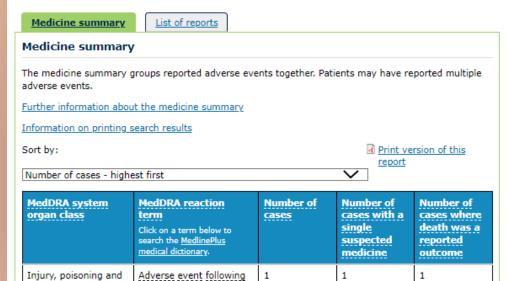
Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

immunisation

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 605490 | 17/08/2021 | 81 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Investigations | Blood pressure decreased | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 606330 | 18/08/2021 | 87 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Blood pressure decreased Cardiogenic shock Somnolence |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

<u>Medicine summary</u>

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Haemoptysis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 606351 | 18/08/2021 | 66 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | DyspnoeaHaemoptysisPyrexiaRespiratory failure |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Vertebral artery dissection | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 605823 | 18/08/2021 | 45 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected Influvac Tetra (Influenza virus haemagglutinin) - Not suspected | Cerebrovascular accident Vertebral artery dissection |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

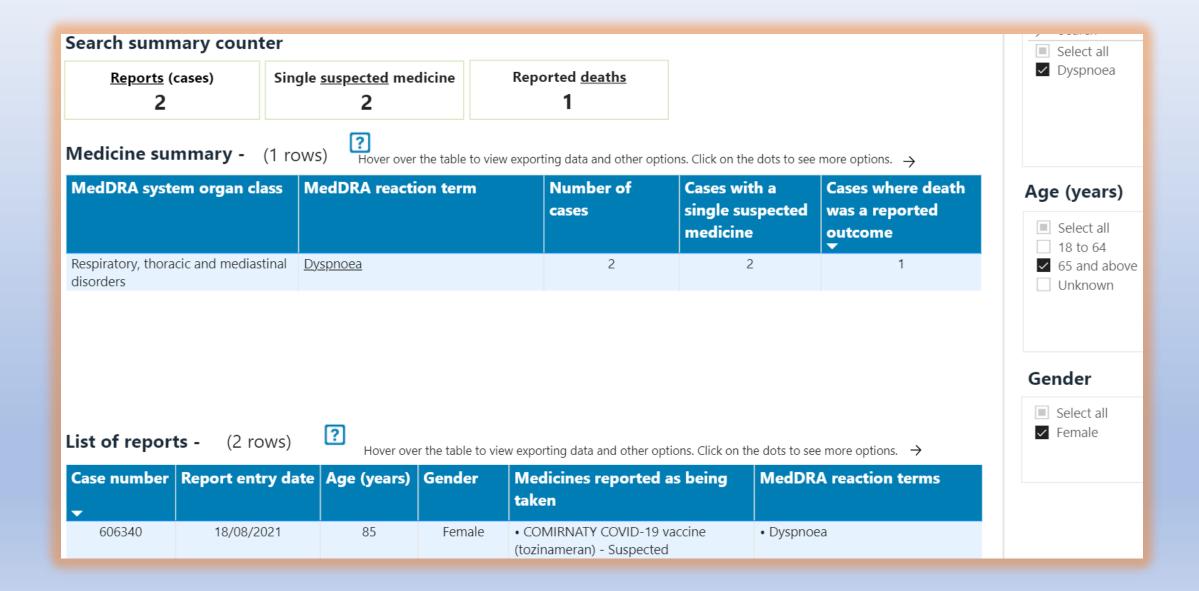
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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Infections and infestations | Pneumonia | 1 | 1 | 1 |

Verifiable death –Male –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 606241 | 18/08/2021 | - | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Delirium Pneumonia |



Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

More information on the search results

| Medicine summar | List of reports | | | | |
|---|---|-----------------|--|--|--|
| Medicine summa | ary | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary | | | | | |
| Information on printing | ng search results | | | | |
| Sort by: | | | | rsion of this | |
| Number of cases - hi | ghest first | | V | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | |
| Infections and infestations | Sepsis | 2 | 2 | 2 | |

1 - Verifiable death –Female –age 811 - Verifiable death –Female –age 65

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 606546 | 19/08/2021 | 81 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Asthenia Bradycardia Cellulitis Hypothermia Immune thrombocytopenia Lethargy Multiple organ dysfunction syndrome Pancytopenia Sepsis |
| 606577 | 19/08/2021 | 65 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardiac arrest Chest pain Fibrin D dimer increased Seizure Sepsis Syncope Thrombocytopenia |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Number of cases - highest first

Sort by:

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| | repor | | | |

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 606973 | 19/08/2021 | 71 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease progression |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summa | <u>List of reports</u> | | | |
|----------------------------------|---|---------------------|--|--|
| Medicine summ | ary | | | |
| The medicine summadverse events. | ary groups reported adverse ev | ents together. Pati | ents may have re | ported multiple |
| Further information | about the medicine summary | | | |
| Information on print | ing search results | | | |
| Sort by: | | | Print ve | rsion of this |
| Number of cases - I | nighest first | | <u> </u> | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
| Cardiac disorders | Acute myocardial infarction | 2 | 2 | 1 |

Verifiable death –Female –age 67

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 606986 | 19/08/2021 | 67 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Acute myocardial infarction Dyspnoea Influenza like illness Rhinorrhoea |

we know this is the case that had a death reported also as all reactions for this person had a death reported too

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 608051 | 20/08/2021 | 95 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 22/08/2021 - 22/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

<u>Medicine summary</u>

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Subarachnoid haemorrhage | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 608638 | 22/08/2021 | 69 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Coma scale abnormal Headache Hypertensive emergency Ruptured cerebral aneurysm Subarachnoid haemorrhage |

■ <u>5 medicines selected</u> between 23/08/2021 - 23/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Cardiac disorders

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

dictionary.

Pulseless electrical activity

More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Sort by: Print version of this report Number of cases - highest first ~ MedDRA MedDRA reaction term **Number of Number of** Number of system organ cases where cases with a cases Click on a term below to search the MedlinePlus medical class single death was a

suspected

medicine

reported

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 609053 | 23/08/2021 | 80 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Acute kidney injury Concomitant disease aggravated Pulmonary embolism Pulseless electrical activity Troponin increased |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Pulmonary oedema | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 609484 | 24/08/2021 | 92 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Acute coronary syndrome Cardiac arrest Pneumonia Pulmonary oedema |

■ <u>5 medicines selected</u> between 24/08/2021 - 24/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|---|-----------------|--|--|
| General disorders and administration site conditions | Organ failure | 1 | 1 | 1 |

Verifiable death -Female -age undiscloseed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 610007 | 24/08/2021 | - | F | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Organ failure Sepsis |

■ <u>5 medicines selected</u> between 24/08/2021 - 24/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Renal and urinary disorders | Renal failure | 2 | 2 | 2 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 609807 | 24/08/2021 | 89 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Dizziness Dyspnoea Lethargy Malaise Pneumonia Renal failure Sepsis |

■ <u>5 medicines selected</u> between 24/08/2021 - 24/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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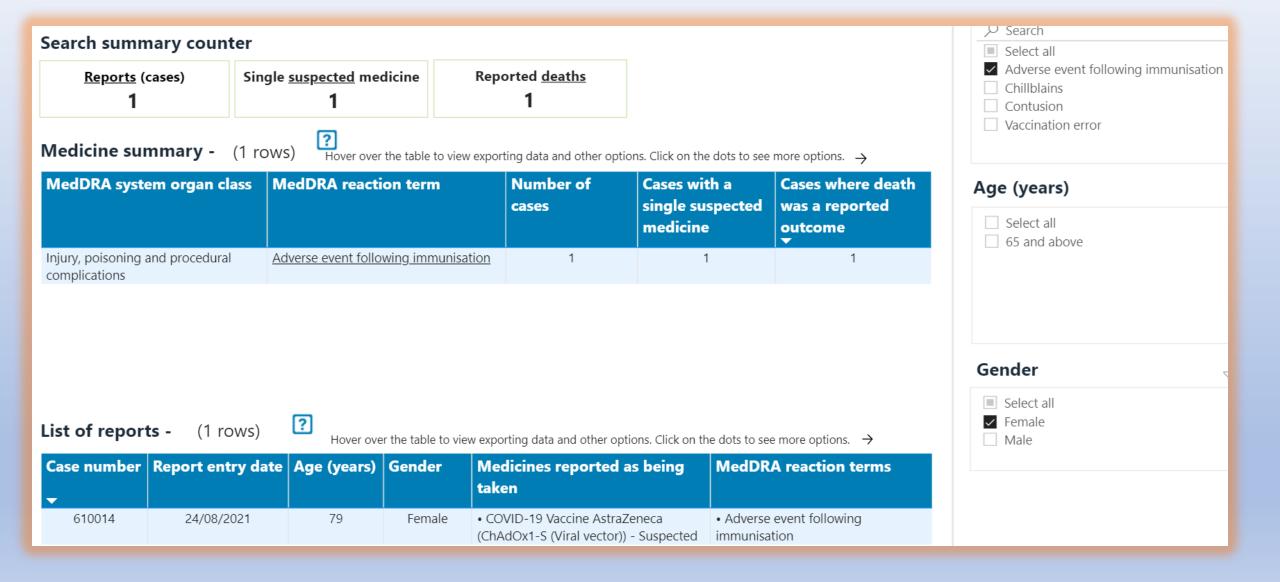
Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Gastrointestinal disorders | Dysphagia | 2 | 2 | 1 |

Verifiable death –Male –age 56

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 609817 | 24/08/2021 | 56 | М | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | DysphagiaDyspnoeaMalaiseVomiting |

We know this case had a death reported also because all other reactions also had a death reported



Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 610491 | 25/08/2021 | 63 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Tradename not specified (apixaban) - Not suspected Tradename not specified (atorvastatin) - Not suspected Tradename not specified (moxonidine) - Not suspected Coveram (amlodipine besilate; perindopril arginine) - Not suspected Xigduo XR (dapagliflozin propanediol monohydrate; metformin hydrochloride) - Not suspected | Cardiac arrest Meningitis pneumococcal Septic shock Streptococcus test positive |

■ <u>5 medicines selected</u> between 25/08/2021 - 25/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

system organ

Cardiac disorders

class

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

| Medicine summary | <u>List of reports</u> | | | |
|--------------------------------------|------------------------|-----------------------|---------------------|------------------|
| Medicine summar | у | | | |
| The medicine summary adverse events. | groups reported adve | erse events together. | Patients may have r | eported multiple |
| Further information abo | ut the medicine summ | <u>nary</u> | | |
| Information on printing | search results | | | |
| Sort by: | | | Print v | ersion of this |
| Number of cases - high | est first | | ~ | |
| MedDRA M | edDRA reaction ter | m Number of | Number of | Number of |

Click on a term below to search

the MedlinePlus medical

Myocardial ischaemia

dictionary.

cases

single

suspected

medicine

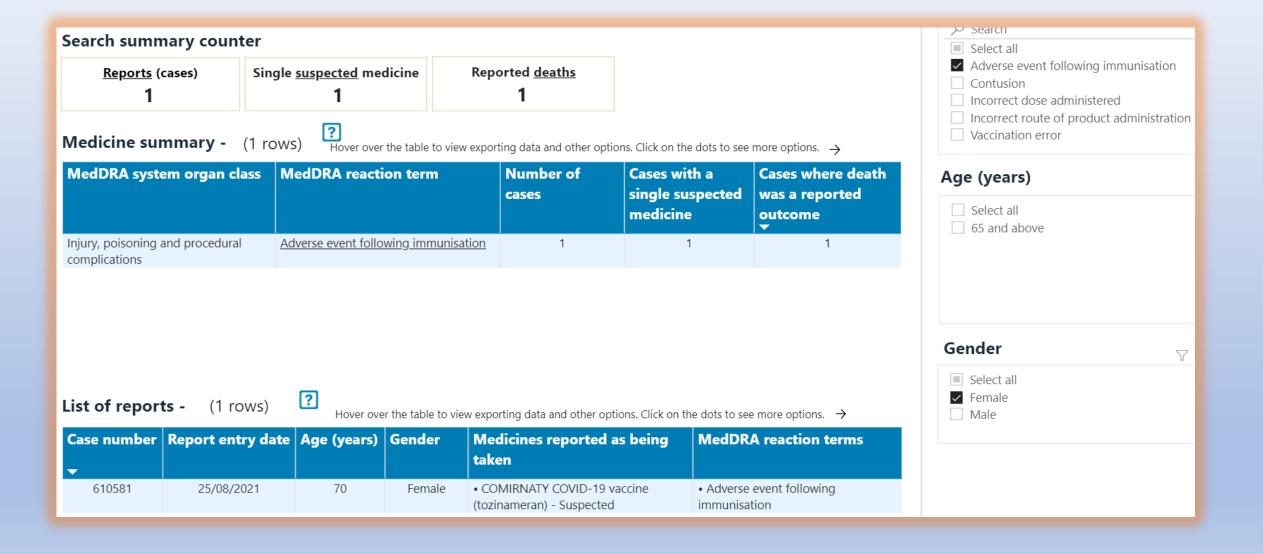
cases where

death was a

reported

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 610431 | 25/08/2021 | 44 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Headache Injection site pain Lethargy Myocardial ischaemia Nasopharyngitis |



■ <u>5 medicines selected</u> between 26/08/2021 - 26/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Myocardial fibrosis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 611057 | 26/08/2021 | 45 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Arteriosclerosis coronary artery Myocardial fibrosis |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 611939 | 27/08/2021 | 49 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Pericardial haemorrhage | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 612314 | 27/08/2021 | 91 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Pericardial haemorrhage |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural immunisation Adverse event following immunisation | | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 613029 | 29/08/2021 | 76 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 29/08/2021 - 29/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Gastrointestinal disorders | Intestinal ischaemia | 1 | 1 | 1 |

Verifiable death -Female -age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 613025 | 29/08/2021 | - | F | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Intestinal ischaemia |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Cerebral infarction | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 613011 | 29/08/2021 | 89 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cerebral infarction Decreased appetite Lethargy Oxygen saturation decreased Somnolence |

■ <u>5 medicines selected</u> between 29/08/2021 - 29/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|---|-----------------|--|--|
| Infections and infestations | Sepsis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 613030 | 29/08/2021 | 67 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Concomitant disease aggravated Sepsis |

■ 5 medicines selected between 30/08/2021 - 30/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Arteriosclerosis coronary artery | 1 | 1 | 1 |

Verifiable death -Male -age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 613388 | 30/08/2021 | - | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Arteriosclerosis coronary artery |

■ <u>5 medicines selected</u> between 30/08/2021 - 30/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 0 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 613371 | 30/08/2021 | 44 | М | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Cardiac arrest |

■ <u>5 medicines selected</u> between 30/08/2021 - 30/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|---|-----------------|--|--|
| Blood and lymphatic system disorders | Thrombosis with thrombocytopenia syndrome | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 613712 | 30/08/2021 | 59 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebral artery thrombosis Cerebrovascular accident Fibrin D dimer increased Hydrocephalus Thrombocytopenia Thrombosis with thrombocytopenia syndrome |

■ 5 medicines selected between 30/08/2021 - 30/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\boldsymbol{1}$

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Respiratory failure | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 613372 | 30/08/2021 | 87 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Respiratory failure |

■ 5 medicines selected between 30/08/2021 - 30/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Subarachnoid haemorrhage | 1 | 1 | 1 |

Verifiable death -Female -age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 613645 | 30/08/2021 | - | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Subarachnoid haemorrhage |

■ <u>5 medicines selected</u> between 30/08/2021 - 30/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|---|-----------------|--|--|
| Infections and infestations | Urosepsis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 613895 | 30/08/2021 | 69 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Tradename not specified (colecalciferol) - Not suspected Tradename not specified (fenofibrate) - Not suspected Tradename not specified (linagliptin) - Not suspected Tradename not specified (Macrogol) - Not suspected Tradename not specified (magnesium) - Not suspected Tradename not specified (mirtazapine) - Not suspected Tradename not specified (mirtazapine) - Not suspected Tradename not specified (omeprazole) - Not suspected Tradename not specified (omeprazole) - Not suspected Tradename not specified | • <u>Urosepsis</u> |

■ 1 medicine selected between 30/08/2021 - 30/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

<u>Medicine summary</u>

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 613462 | 30/08/2021 | 64 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

■ 5 medicines selected between 30/08/2021 - 30/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 18

Number of cases with a single <u>suspected</u> medicine: **18**Number of cases where <u>death</u> was a reported outcome: **1**

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

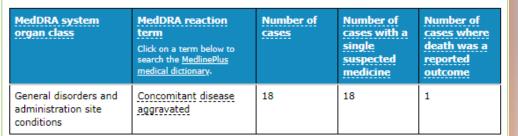
'----<u>'</u>

Sort by:

Print version of this report

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Number of cases - highest first



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 614324 | 30/08/2021 | 58 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease aggravated Dizziness |

■ 5 medicines selected between 31/08/2021 - 31/08/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| General disorders and administration site conditions Concomitant disease progression | | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 614690 | 31/08/2021 | 66 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Duodart 500/400 (dutasteride; tamsulosin hydrochloride) - Not suspected Ventolin CFC-free Inhaler (salbutamol sulfate) - Not suspected | Cerebral haematoma Concomitant disease progression Headache |

■ 5 medicines selected between 01/09/2021 - 01/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single <u>suspected</u> medicine: 1

Number of cases where <u>death</u> was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Cerebral artery thrombosis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 615211 | 01/09/2021 | 54 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebral artery thrombosis Cerebral infarction Fibrin D dimer increased Headache Hyperhidrosis Myalgia Pyrexia Thrombocytopenia Thrombosis with thrombocytopenia syndrome Troponin I increased |

■ 5 medicines selected between 01/09/2021 - 01/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Number of cases - highest first

Print version of this report

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Cardiac disorders | Coronary artery disease | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 615222 | 01/09/2021 | 78 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Coronary artery disease |

■ 5 medicines selected between 01/09/2021 - 01/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | nd mediastinal | | 2 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 615790 | 01/09/2021 | 76 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | AstheniaFacial paralysisPharyngeal swelling |

Verifiable death -Male -age undisclosed

| Search summary cour | nter | | | | Select all |
|--|---|---|--|--|--|
| Reports (cases) 1 Medicine summary - | Single <u>suspected</u> medicine 1 (1 rows) Hover over the tal | 1 | | | ☐ Arrhythmia☐ Atrial fibrillation☐ Coronary artery disease✓ Myocarditis☐ Myopericarditis |
| MedDRA system organ | | Number of cases | Cases with a single suspected medicine | Cases where death was a reported outcome | Age (years) Select all Unknown |
| Cardiac disorders | <u>Myocarditis</u> | 1 | 1 | 1 | |
| | | | | | Gender Select all |
| List of reports - (1 r | ☐ Female ✓ Male | | | | |
| Case number Report en | ntry date Age (years) Gen | der Medicines reported taken | as being MedDR | A reaction terms | |
| 615875 1/09/3 | 2021 - 1 | • COMIRNATY COVID-19 v (tozinameran) - Suspected | , | ditis | |

| Search sumn | nary counter | r | | | | | Select all |
|-----------------------------------|-------------------|--------------------------------------|--------------|---|--|--|--|
| Reports (o | | ingle <u>suspected</u> med 1 rows) | | Reported <u>deaths</u> 1 exporting data and other option | ons. Click on the dats to see | more entions | ☐ Chest discomfort ☐ Chest pain ☐ Chills ☑ Concomitant disease aggravated ☐ Discomfort |
| MedDRA syste | | | | Number of cases | Cases with a single suspected medicine | Cases where death was a reported outcome | Age (years) Select all 12 to 17 |
| General disorders site conditions | and administratio | n <u>Concomitant disease</u> | e aggravated | 1 | 1 | 1 | ✓ 18 to 64 Unknown |
| | | | | | | | Gender |
| List of report | | nover over | | v exporting data and other opt | | | ■ Select all □ Female ☑ Male |
| Case number → | Report entry | date Age (years) | | Medicines reported a taken | s being MedDR | A reaction terms | |
| 615369 | 1/09/2021 | 54 | Male | COMIRNATY COVID-19 v. (tozinameran) - Suspected | 5 | nitant disease aggravated | |

■ <u>5 medicines selected</u> between 02/09/2021 - 02/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|---|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Pulmonary congestion | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 615920 | 02/09/2021 | 76 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardiac arrest Chest pain Dyspnoea Pneumothorax Pulmonary congestion Pulmonary embolism |

■ <u>5 medicines selected</u> between 02/09/2021 - 02/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Haemorrhagic stroke | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 616146 | 02/09/2021 | 83 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Haemorrhagic stroke Headache |

■ <u>5 medicines selected</u> between 02/09/2021 - 02/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 6

Number of cases with a single <u>suspected</u> medicine: 6

Number of cases where <u>death</u> was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Number of cases - highest first

Sort by:

Print version of this report

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of Cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Myocarditis | 6 | 6 | 1 |

Verifiable death –Male –age 17

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 616124 | 02/09/2021 | 17 | М | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Headache Malaise Myocarditis |

we know this report had a death associated due to the other reactions having a death reported also

■ 5 medicines selected between 02/09/2021 - 02/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 11

Number of cases with a single <u>suspected</u> medicine: **11**Number of cases where death was a reported outcome: **1**

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Gastrointestinal disorders | Vomiting | 11 | 11 | 1 |

Verifiable death -Male -age 74

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 616464 | 02/09/2021 | 74 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | DiarrhoeaVomiting |

we know this report had a death reported also as other reaction had a death associated with it too

■ 5 medicines selected between 03/09/2021 - 03/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

<u>Medicine summary</u>

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 617068 | 03/09/2021 | 41 | М | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Cardiac arrest |

■ 5 medicines selected between 05/09/2021 - 05/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Myocardial ischaemia | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 617841 | 05/09/2021 | 60 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardiac arrest Chest pain Dyspnoea Myocardial ischaemia |

■ <u>5 medicines selected</u> between 05/09/2021 - 05/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| Number of cases - nigh | | | | |
|---|--|-----------------|--|--|
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
| Respiratory, thoracic and mediastinal disorders | Pleural effusion | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 617751 | 05/09/2021 | 84 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease aggravated Fibrin D dimer increased Pleural effusion Thrombocytopenia |

■ <u>5 medicines selected</u> between 05/09/2021 - 05/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

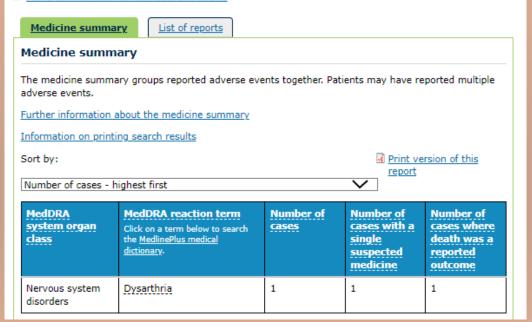
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 617755 | 05/09/2021 | 82 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Abdominal pain upper Atrial fibrillation Dysarthria Vomiting |

■ 5 medicines selected between 06/09/2021 - 06/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Sort by: Print version of this report Number of cases - highest first $\overline{}$ MedDRA Number of MedDRA reaction term **Number of Number of** system organ Click on a term below to search cases cases with a cases where class single death was a the MedlinePlus medical dictionary. suspected reported medicine outcome Myocardial ischaemia Cardiac disorders

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 618181 | 06/09/2021 | 62 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Diarrhoea Fatigue Headache Hot flush Myocardial ischaemia |

■ 5 medicines selected between 06/09/2021 - 06/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Cardiac disorders

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

dictionary.

Acute myocardial infarction

■ More information on the search results



suspected

medicine

reported

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 618211 | 06/09/2021 | 69 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Acute myocardial infarction |

■ <u>5 medicines selected</u> between 06/09/2021 - 06/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

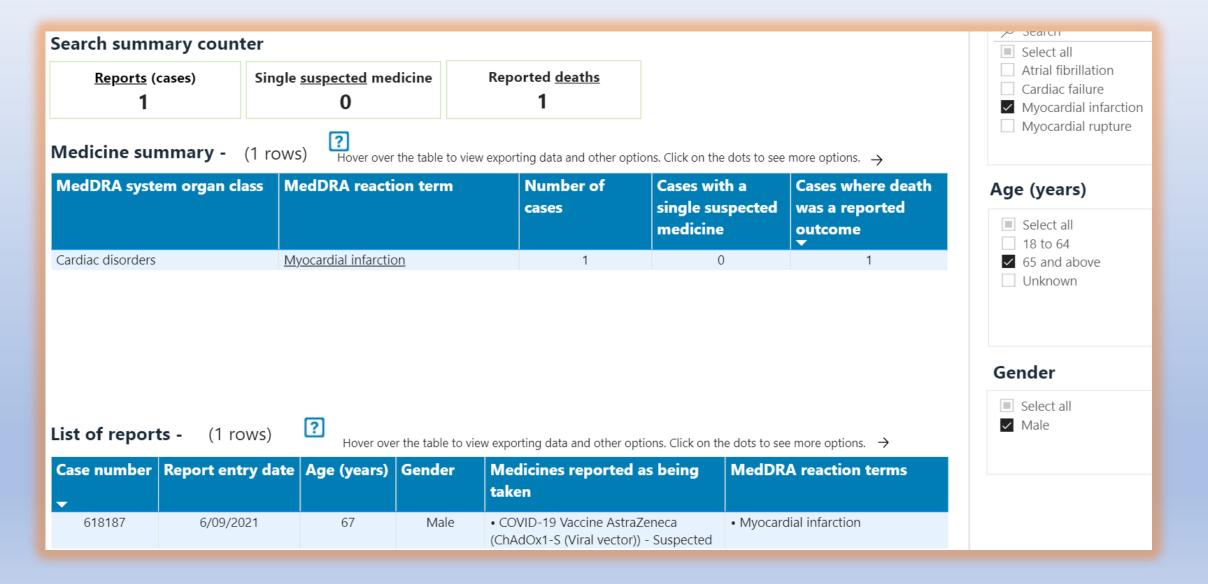
Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Gastrointestinal disorders | Retching | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 618180 | 06/09/2021 | 79 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | DiarrhoeaRetchingSubduralhaematoma |



■ 1 medicine selected between 06/09/2021 - 06/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results

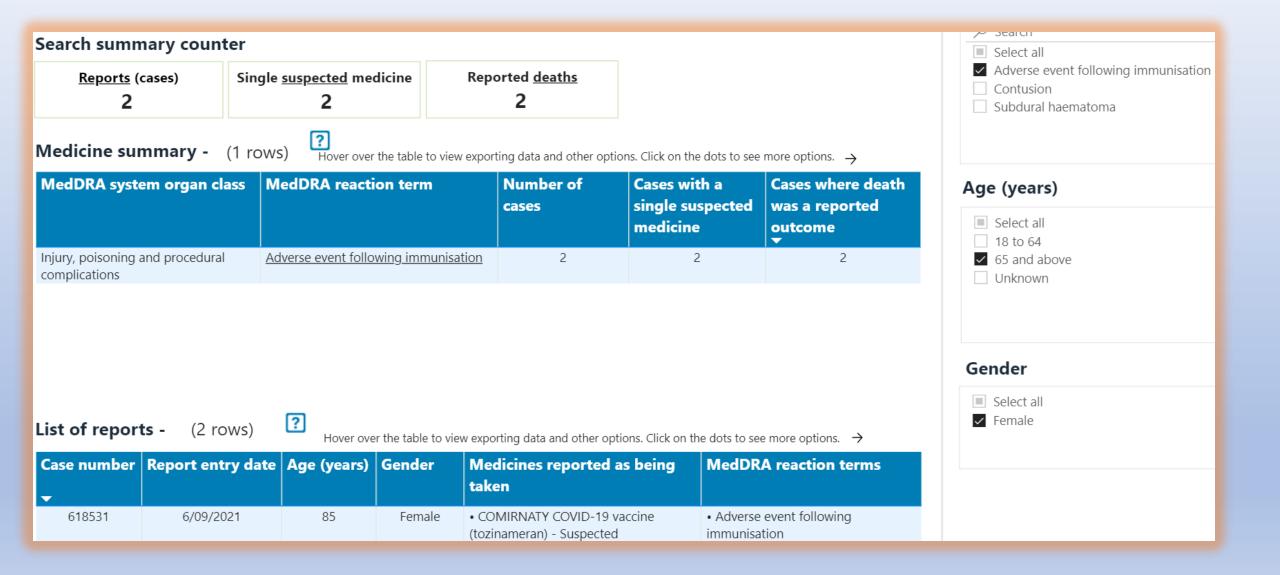
Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Sort by: Print version of this report Number of cases - highest first MedDRA system MedDRA reaction Number of Number of Number of

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Malaise | 2 | 2 | 1 |

Verifiable death –Female –age 92

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 618446 | 06/09/2021 | 92 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation Malaise Nausea |

we know this case had a dearth reported also because of the other reactions also having a death reported



■ <u>5 medicines selected</u> between 07/09/2021 - 07/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Vertebrobasilar stroke | 1 | 1 | 1 |

Verifiable death –Male –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 619817 | 07/09/2021 | - | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Vertebrobasilar stroke |

■ <u>5 medicines selected</u> between 07/09/2021 - 07/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

Nervous system disorders

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single <u>suspected</u> medicine: 1

Number of cases where <u>death</u> was a reported outcome: 1

Cerebrovascular accident

More information on the search results

| Medicine summ | List of reports | | | | | | | |
|-----------------------------------|---|-----------------|---|---|--|--|--|--|
| Medicine summary | | | | | | | | |
| The medicine summ adverse events. | The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | |
| Further information | about the medicine summary | | | | | | | |
| Information on print | ting search results | | | | | | | |
| Sort by: | | | | rsion of this | | | | |
| Number of cases - | highest first | | report | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected | Number of cases where death was a reported | | | | |

medicine

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 619579 | 07/09/2021 | 71 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected FLUAD QUAD (Influenza virus haemagglutinin) Suspected | Asthenia Cerebrovascular accident |

■ 5 medicines selected between 08/09/2021 - 08/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 620368 | 08/09/2021 | 75 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Cardiac arrest |

■ <u>5 medicines selected</u> between 08/09/2021 - 08/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

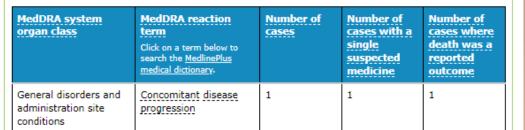
Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 620090 | 08/09/2021 | 83 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease progression Lymphoma |

■ 5 medicines selected between 09/09/2021 - 09/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 1 | 1 |

Verifiable death -Female -age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 620719 | 09/09/2021 | | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Tradename not specified (apixaban) - Not suspected Tradename not specified (digoxin) - Not suspected Tradename not specified (furosemide (frusemide)) - Not suspected Tradename not specified (spironolactone) - Not suspected Alvesco (ciclesonide) - Not suspected Alvesco (ciclesonide) - Not suspected Metoprolol (metoprolol tartrate) - Not suspected Salbutamol (salbutamol) - Not suspected | Concomitant disease progression |

■ 5 medicines selected between 09/09/2021 - 09/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Investigations | SARS-CoV-2 test positive | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 620700 | 09/09/2021 | 48 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Fibrin D dimer increased Immune thrombocytopenia Pulmonary embolism SARS-CoV-2 test positive |

■ 1 medicine selected between 09/09/2021 - 09/09/2021.

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

■ 1 MedDRA Reaction Term selected.

Search results

Nervous system disorders

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

Cerebrovascular accident

■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report Number of cases - highest first $\overline{}$ Number of MedDRA MedDRA reaction term **Number of Number of** system organ Click on a term below to search cases cases with a cases where class the MedlinePlus medical single death was a dictionary. suspected reported

medicine

outcome

Verifiable death -Female -age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 621253 | 09/09/2021 | - | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cerebrovascular accident |

■ 1 medicine selected between 09/09/2021 - 09/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 2 | 2 | 1 |

Verifiable death –Male –age 65

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 621287 | 09/09/2021 | 65 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Tradename not specified (atorvastatin) - Not suspected Coveram (amlodipine besilate; perindopril arginine) - Not suspected Metformin (metformin hydrochloride) - Not suspected | Adverse event following immunisation |

We know this is the case that also had a death reported as the other case reported another reaction that did not have a death associated with it

■ <u>5 medicines selected</u> between 11/09/2021 - 11/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 1 | 1 | 1 |

| | | | | T | 22022 |
|----------------|----------------------|--------------|--------|--|---|
| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
| 622436 | 11/09/2021 | 67 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Ardix Gliclazide 60mg MR (gliclazide) - Not suspected Cartia (aspirin) - Not suspected Ferrograd C (ferrous sulfate; sodium ascorbate) - Not suspected Lipitor (atorvastatin calcium) - Not suspected Metex XR (metformin hydrochloride) - Not suspected Minax (metoprolol tartrate) - Not suspected Minax (metoprolol tartrate) - Not suspected Salpraz (pantoprazole) - Not suspected Span-k (potassium chloride) - Not suspected Uremide (furosemide (frusemide)) - Not suspected Uremide (furosemide | Cerebrovascular accident Concomitant disease aggravated Myocardial ischaemia Syncope |

■ 5 medicines selected between 13/09/2021 - 13/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Cardiac disorders

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

Cardiovascular disorder

More information on the search results

| Medicine summa | List of reports | | | |
|---------------------------------|---|---------------------|---|---|
| Medicine summ | nary | | | |
| The medicine summa | ary groups reported adverse ev | ents together. Pati | ients may have re | ported multiple |
| Further information | about the medicine summary | | | |
| Information on print | ing search results | | | |
| Sort by: | | | Print ve report | rsion of this |
| Number of cases - I | highest first | | V | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected | Number of cases where death was a reported |

2

1 - Verifiable death -Male -age 67

2 - Verifiable death -Female -age 75

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 623386 | 13/09/2021 | 67 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardiovascular disorder |
| 623399 | 13/09/2021 | 75 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardiovascular disorder |

■ <u>5 medicines selected</u> between 13/09/2021 - 13/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Pericardial haemorrhage | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 623046 | 13/09/2021 | 89 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Aortic dissection Pericardial haemorrhage |

■ 5 medicines selected between 13/09/2021 - 13/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: ${f 1}$

■ More information on the search results

Medicine summary List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| General disorders and administration site | Concomitant disease progression | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 622885 | 13/09/2021 | 67 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease progression |

■ 5 medicines selected between 13/09/2021 - 13/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 623212 | 13/09/2021 | 83 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Haemorrhage intracranial |

■ 5 medicines selected between 15/09/2021 - 15/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Medicine summary

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

Medicine summary List

List of reports

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 624541 | 15/09/2021 | 51 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Fosamax Plus D-Cal (alendronate sodium; calcium carbonate; colecalciferol) - Not suspected Mogadon (nitrazepam) - Not suspected Stilnox (zolpidem tartrate) - Not suspected Thiamine (thiamine hydrochloride) - Not suspected | Adverse event following immunisation |

■ 5 medicines selected between 16/09/2021 - 16/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 1 | 1 |

Verifiable death –Female –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 625877 | 16/09/2021 | - | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease progression Deep vein thrombosis Fall Pneumonia aspiration Pulmonary embolism |

■ 5 medicines selected between 16/09/2021 - 16/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Myocardial infarction | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 625386 | 16/09/2021 | 50 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Chest pain Myocardial infarction Myoclonus Ventricular tachycardia |

■ <u>5 medicines selected</u> between 16/09/2021 - 16/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------|--|-----------------|--|--|
| Investigations | C-reactive protein increased | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 625843 | 16/09/2021 | 73 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Abdominal pain C-reactive protein increased Diarrhoea Multiple organ dysfunction syndrome |

■ <u>5 medicines selected</u> between 16/09/2021 - 16/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 625235 | 16/09/2021 | 84 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cerebrovascular accident |

■ 5 medicines selected between 16/09/2021 - 16/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Medicine summary

Cardiac disorders

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

dictionary.

Cardiac arrest

List of reports

■ More information on the search results

Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: <u>report</u> $\overline{}$ Number of cases - highest first MedDRA **Number of Number of** Number of MedDRA reaction term cases with a system organ cases cases where Click on a term below to search class the MedlinePlus medical death was a single

suspected

medicine

reported

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 625161 | 16/09/2021 | 64 | М | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected FLUAD QUAD (Influenza virus haemagglutinin) - Not suspected | Cardiac arrest Malaise Pneumonia |

■ <u>5 medicines selected</u> between 16/09/2021 - 16/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 625997 | 16/09/2021 | 71 | М | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | Adverse event following immunisation |

■ 5 medicines selected between 17/09/2021 - 17/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

■ More information on the search results

<u>Medicine summary</u>

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 2 | 2 | 2 |

1 - Verifiable death –Male –age 832 - Verifiable death –Male –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 626452 | 17/09/2021 | 83 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation Aortic aneurysm |
| 626537 | 17/09/2021 | - | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 17/09/2021 - 17/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Haemorrhage intracranial | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 626171 | 17/09/2021 | 53 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Haemorrhage intracranial |

■ <u>5 medicines selected</u> between 17/09/2021 - 17/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Number of cases - highest first

Print version of this report

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| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 626642 | 17/09/2021 | 56 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Concomitant disease progression Pain in extremity |

■ <u>5 medicines selected</u> between 17/09/2021 - 17/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Medicine summary

class

Cardiac disorders

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

List of reports

the MedlinePlus medical

dictionary.

Cardiac arrest

■ More information on the search results

| Medicine summa | ary | | | |
|------------------------------------|---|---------------------|------------------------|-----------------------|
| The medicine summa adverse events. | ry groups reported adverse ev | ents together. Pati | ients may have re | ported multiple |
| Further information a | bout the medicine summary | | | |
| Information on printing | ng search results | | | |
| Sort by: | | | Print ve | ersion of this |
| Number of cases - hi | ghest first | | ✓ ICDUIT | |
| MedDRA system organ | MedDRA reaction term Click on a term below to search | Number of cases | Number of cases with a | Number of cases where |

cases where

death was a

reported

outcome

single

suspected

medicine

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 626403 | 17/09/2021 | 73 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Acute myocardial infarction Cardiac arrest Hypoaesthesia Thrombocytopenia Troponin increased |

■ 5 medicines selected between 17/09/2021 - 17/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| 5 | ledDRA ystem organ lass | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|-------------------------------|---|-----------------|--|--|
| ٧ | ascular disorders | Thrombosis | 3 | 3 | 1 |

Verifiable death –Female –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 626646 | 17/09/2021 | - | F | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Deep vein thrombosis Pulmonary embolism Thrombosis |

■ 5 medicines selected between 18/09/2021 - 18/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 1 | 0 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 626784 | 18/09/2021 | 82 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebrovascular accident |

■ <u>5 medicines selected</u> between 19/09/2021 - 19/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Myoclonus | 1 | 0 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 627211 | 19/09/2021 | 65 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Decreased appetite Deep vein thrombosis Myoclonus Pulmonary embolism Somnolence Thrombocytopenia Vomiting |

■ 5 medicines selected between 21/09/2021 - 21/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

class

Nervous system disorders

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

the MedlinePlus medical

Lacunar infarction

dictionary.

■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report Number of cases - highest first $\overline{}$ MedDRA MedDRA reaction term Number of **Number of Number of** cases where system organ cases cases with a Click on a term below to search

single

suspected medicine

death was a

reported

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 628900 | 21/09/2021 | 91 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Lacunar infarction |

■ <u>5 medicines selected</u> between 21/09/2021 - 21/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

<u>Medicine summary</u>

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Congenital, familial and genetic disorders | Factor V Leiden mutation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 628504 | 21/09/2021 | 74 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Abdominal pain Deep vein thrombosis Factor V Leiden mutation Malaise Pulmonary embolism |

■ 5 medicines selected between 22/09/2021 - 22/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

List of reports

■ More information on the search results

Medicine summary

Medicine summary

Sort by:

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

| Nu | mber of cases - h | nighest first | report | | |
|------------|--|--------------------------|-----------------|--|--|
| 5 y | MedDRA system organ class Click on a term below to search the MedlinePlus medical dictionary. | | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
| | rvous system sorders | Subarachnoid haemorrhage | 1 | 1 | 1 |

Print version of this

| | ase umber | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|---|--------------|----------------------|--------------|--------|---|--|
| 6 | 29365 | 22/09/2021 | 70 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Dizziness Headache Intracranial aneurysm Subarachnoid haemorrhage |

■ <u>5 medicines selected</u> between 22/09/2021 - 22/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Respiratory arrest | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 629243 | 22/09/2021 | 88 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Respiratory arrest |

■ 5 medicines selected between 24/09/2021 - 24/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

Investigations

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

White blood cell count

increased

■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: $\overline{}$ Number of cases - highest first Number of MedDRA system MedDRA reaction term **Number of** Number of organ class cases cases with a cases where Click on a term below to search death was a the MedlinePlus medical single dictionary. suspected reported medicine outcome

Verifiable death –Female –age 68

Case Medicines reported as Report Age Gender MedDRA reaction number entry date (yrs) being taken terms Click on a term below to search the MedlinePlus medical dictionary. 24/09/2021 630936 F COMIRNATY COVID-· C-reactive protein 68 19 vaccine increased Haemoglobin (tozinameran) -Suspected decreased Intestinal obstruction · Platelet count increased Pneumonitis aspiration Pulmonary embolism Vomiting · White blood cell count increased

■ <u>5 medicines selected</u> between 24/09/2021 - 24/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Vascular disorders | Aortic aneurysm rupture | 1 | 1 | 1 |

Verifiable death –Male –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 631086 | 24/09/2021 | - | М | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Aortic aneurysm rupture |

■ 5 medicines selected between 25/09/2021 - 25/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| | dDRA system an class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------|-------------------------|--|-----------------|--|--|
| Inve | estigations | Liver function test abnormal | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 631624 | 25/09/2021 | 46 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Acute pulmonary oedema Atrial fibrillation Cardiogenic shock Fibrin D dimer increased Hyponatraemia Joint swelling Liver function test abnormal Lung abscess Multiple organ dysfunction syndrome Orthopnoea Pleural effusion Productive cough Sepsis Tachycardia |

■ 5 medicines selected between 25/09/2021 - 25/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

List of reports Medicine summary Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report Number of cases - highest first $\overline{}$ MedDRA **Number of** Number of MedDRA reaction term **Number of** cases with a cases where system organ cases Click on a term below to search class the MedlinePlus medical single death was a dictionary. suspected reported medicine outcome Cardiac disorders Cardiac arrest

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 631625 | 25/09/2021 | 19 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Blood fibrinogen increased Brain hypoxia Cardiac arrest Haemoglobin decreased Red blood cell count decreased |

■ 5 medicines selected between 26/09/2021 - 26/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

List of reports

■ More information on the search results

Medicine summary Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Respiratory arrest | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 632170 | 26/09/2021 | 76 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Respiratory arrest |

■ <u>5 medicines selected</u> between 27/09/2021 - 27/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Subarachnoid haemorrhage | 1 | 1 | 1 |

Print version of this

report

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| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 632351 | 27/09/2021 | 52 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Subarachnoid haemorrhage Troponin I increased |

■ <u>5 medicines selected</u> between 27/09/2021 - 27/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summary | <u>List of reports</u> | | | | | | | | |
|---|------------------------|---------------------------------|------------------------------|--|--|--|--|--|--|
| Medicine summary | | | | | | | | | |
| The medicine summary groadverse events. | ups reported adve | rse events together. Patients m | ay have reported multiple | | | | | | |
| Further information about t | he medicine summ | <u>nary</u> | | | | | | | |
| Information on printing search results | | | | | | | | | |
| Sort by: | | I | Print version of this report | | | | | | |
| Number of cases - highest | first | ~ | | | | | | | |

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Vascular disorders | Arteriosclerosis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 632340 | 27/09/2021 | 80 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Arteriosclerosis Cardiac arrest |

■ 5 medicines selected between 27/09/2021 - 27/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 6

Number of cases with a single suspected medicine: 5

Number of cases where $\underline{\text{death}}$ was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Vascular disorders | Deep vein thrombosis | 6 | 5 | 1 |

Verifiable death -Male -age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 632776 | 27/09/2021 | - | М | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Deep vein thrombosis Pulmonary embolism |

■ 5 medicines selected between 28/09/2021 - 28/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

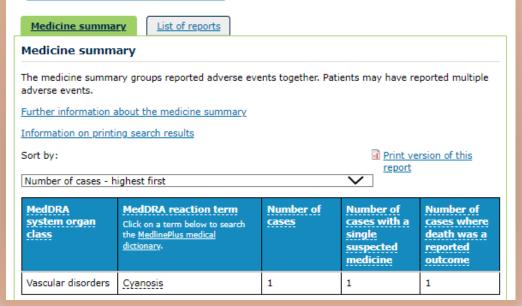
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 633189 | 28/09/2021 | 57 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Aortic dissection Chest pain Cyanosis Fibrin D dimer increased Hyperhidrosis Hypertension Pain in extremity Seizure |

■ <u>5 medicines selected</u> between 28/09/2021 - 28/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

<u>Medicine summary</u>

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Gastrointestinal disorders | Colitis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 633133 | 28/09/2021 | 64 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Aspiration Colitis Haematemesis Spontaneous bacterial peritonitis Vomiting |

■ <u>5 medicines selected</u> between 28/09/2021 - 28/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Cardiac disorders

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

dictionary.

Cardiac failure

More information on the search results

| Medicine summa | List of reports | | | | | | |
|------------------------------------|--|----------------------|-------------------------------|---|--|--|--|
| Medicine summary | | | | | | | |
| The medicine summa adverse events. | ary groups reported adverse ev | vents together. Pati | ients may have re | ported multiple | | | |
| Further information a | about the medicine summary | | | | | | |
| Information on printi | ng search results | | | | | | |
| Sort by: | | | | rsion of this | | | |
| Number of cases - highest first | | | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical | Number of cases | Number of cases with a single | Number of cases where death was a | | | |

suspected

medicine

reported

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 633266 | 28/09/2021 | 69 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Cardiac failure |

■ 1 medicine selected between 29/09/2021 - 29/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 12

Number of cases with a single <u>suspected</u> medicine: **12**Number of cases where <u>death</u> was a reported outcome: **1**

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Pyrexia | 12 | 12 | 1 |

Verifiable death -Male -age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 634300 | 29/09/2021 | - | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Dyspnoea Pyrexia |

we know this was the case that had a death reported (1/12) because of the other reaction also having a death associated with it

■ 1 medicine selected between 30/09/2021 - 30/09/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Print version of this report

Number of cases - highest first

Sort by:

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease aggravated | 2 | 2 | 1 |

Verifiable death –Male –age 73

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 635096 | 30/09/2021 | 73 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease aggravated Pulmonary embolism |

we know this was the case that had a death reported also as the other reaction reported also had a death reported

■ 5 medicines selected between 01/10/2021 - 01/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|-----------------------------|---|-----------------|--|--|
| Infections and infestations | Urinary tract infection | 1 | 1 | 1 |

| Case num | | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|-------------|----|----------------------|--------------|--------|---|---|
| 6352 | 46 | 01/10/2021 | 81 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease progression Fibrin D dimer increased Multiple organ dysfunction syndrome Pneumonia Thrombocytopenia Urinary tract infection |

■ 1 medicine selected between 01/10/2021 - 01/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Vascular disorders | Hot flush | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 635916 | 01/10/2021 | 42 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation Chills Decreased appetite Hot flush Nausea |

■ 1 medicine selected between 01/10/2021 - 01/10/2021.

Selected medicines

| Trade name | Active ingredients | |
|------------------------|---------------------------------------|--|
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) | |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest firs

| ses - | highest | first | | |
|-------|---------|-------|--|--|
| | | | | |

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 1 | 1 | 1 |

Verifiable death -Male -age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 635326 | 01/10/2021 | - | М | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | Cerebrovascular accident |

■ 5 medicines selected between 01/10/2021 - 01/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 2

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|----------------------------------|--|-----------------|--|--|
| Injury, poisoning and procedural | Adverse event following immunisation | 3 | 3 | 2 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 635457 | 01/10/2021 | 57 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

■ 5 medicines selected between 02/10/2021 - 02/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: ${\bf 3}$

Number of cases where death was a reported outcome: 3

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 3 | 3 | 3 |

- 1 Verifiable death -Female -age 74
 - 2 Verifiable death -Male -age 68
 - 3 Verifiable death -Male -age 62

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 636272 | 02/10/2021 | 74 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease progression Dyspnoea Lethargy Malaise |
| 636307 | 02/10/2021 | 68 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Atrial fibrillation Bradycardia Concomitant disease progression Dyspnoea Hypotension Lethargy |
| 636312 | 02/10/2021 | 62 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Chills Concomitant disease progression Pyrexia Retching |

■ <u>5 medicines selected</u> between 02/10/2021 - 02/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 636053 | 02/10/2021 | 58 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Cardiac arrestDyspnoeaFibrin D dimer increased |

■ <u>5 medicines selected</u> between 02/10/2021 - 02/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Cerebral haemorrhage | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 636296 | 02/10/2021 | 73 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardio-respiratory arrest Cerebral haemorrhage Cerebral mass effect Fall Immune thrombocytopenia Subdural haematoma Thrombocytopenia |

■ <u>5 medicines selected</u> between 03/10/2021 - 03/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Blood and lymphatic system disorders | Thrombocytopenia | 2 | 2 | 2 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 636562 | 03/10/2021 | 80 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Tradename not specified (doxycycline) - Not suspected Tradename not specified (prednisone) - Not suspected Actonel (risedronate sodium) - Not suspected AMCLAVOX DUO FORTE 875/125 (amoxicillin trihydrate; clavulanic acid) - Not suspected Crosuva (rosuvastatin calcium) - Not suspected Metoprolol (metoprolol tartrate) - Not suspected Spiriva (tiotropium bromide monohydrate) - Not suspected Symbicort Turbuhaler 400/12 (budesonide; formoterol (eformoterol) fumarate dihydrate) - Not suspected | Cough Dyspnoea Haemophagocytic lymphohistiocytosis Multiple organ dysfunction syndrome Pyrexia Thrombocytopenia |

■ 5 medicines selected between 03/10/2021 - 03/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

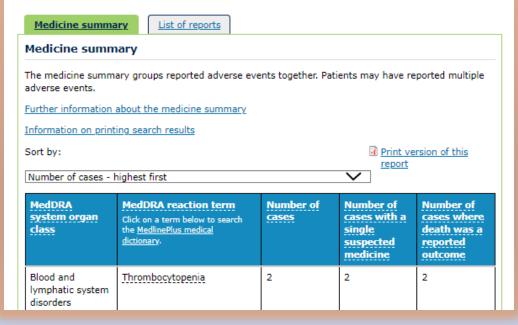
The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 636642 | 03/10/2021 | 63 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Dyspnoea Fibrin D dimer increased Hyperglycaemia Hypoxia Pneumonia Pulmonary embolism SARS-CoV-2 test positive Sepsis Thrombocytopenia Vision blurred |

■ 5 medicines selected between 03/10/2021 - 03/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| - | | | | | | |
|--|--|-----------------|--|--|--|--|
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | |
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 0 | 1 | | |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 636516 | 03/10/2021 | 92 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation Chest pain Fatigue |

■ <u>5 medicines selected</u> between 05/10/2021 - 05/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report Number of cases - highest first $\overline{}$ **Number of** MedDRA MedDRA reaction term Number of Number of system organ cases where cases with a cases Click on a term below to search class the MedlinePlus medical death was a single suspected dictionary. reported medicine outcome Vascular disorders Aortic aneurysm

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 638153 | 05/10/2021 | 79 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected FLUAD QUAD (Influenza virus haemagglutinin) - Suspected | Aortic aneurysm Deep vein thrombosis Haematological malignancy |

■ <u>5 medicines selected</u> between 05/10/2021 - 05/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

<u>'</u>

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|--------------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Respiratory acidosis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 637921 | 05/10/2021 | 50 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease aggravated Respiratory acidosis |

■ <u>5 medicines selected</u> between 06/10/2021 - 06/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

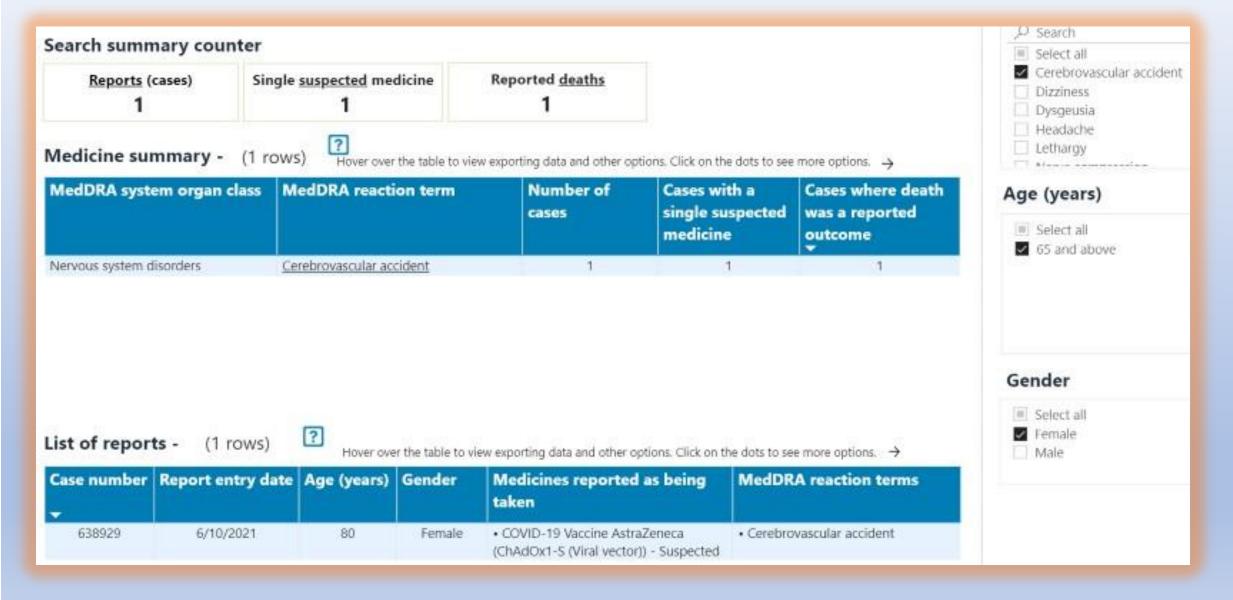
Number of cases with a single suspected medicine: 1

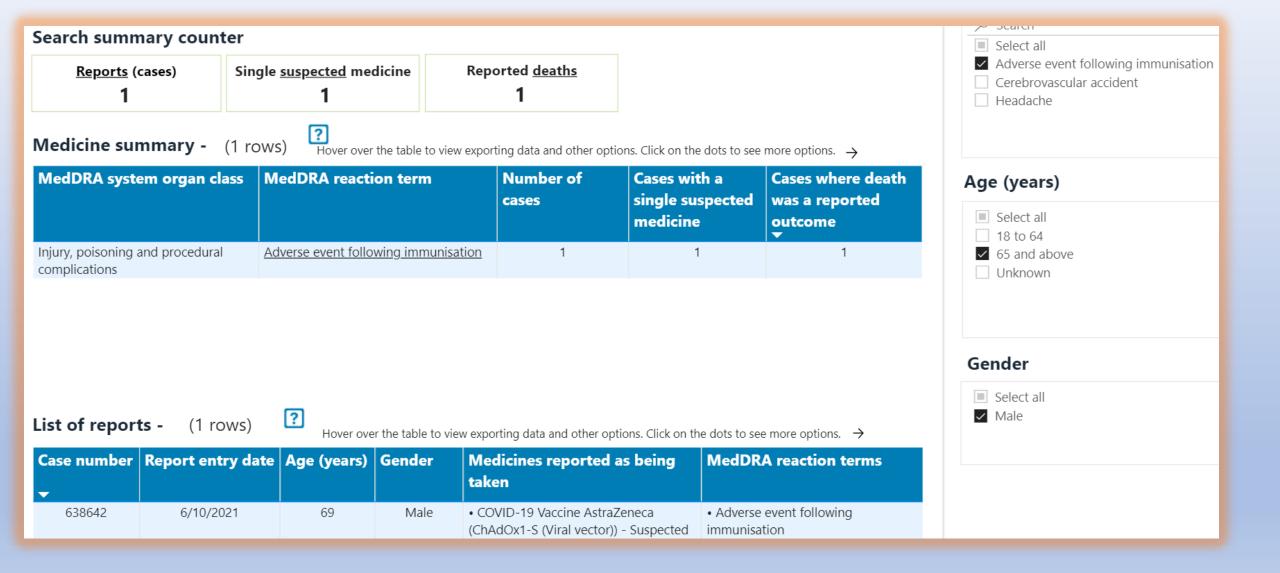
Number of cases where death was a reported outcome: 1

More information on the search results

| Medicine summa | List of reports | | | | | |
|--|---|---------------------|--|--|--|--|
| Medicine summ | Medicine summary | | | | | |
| adverse events. Further information a | ary groups reported adverse even | ents together. Pati | ents may have re | ported multiple | | |
| Information on printi | ng search results | | | | | |
| Sort by: | | | Print ve report | rsion of this | | |
| Number of cases - h | ighest first | | <u> </u> | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | |
| Vascular disorders | Aneurysm ruptured | 1 | 1 | 1 | | |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 638636 | 06/10/2021 | 48 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Abdominal pain upper Aneurysm ruptured Seizure |





■ 5 medicines selected between 07/10/2021 - 07/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

perinatal conditions

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summary | List of reports | | | | | | |
|--|--|--------------------|--|--|--|--|--|
| Medicine summa | ry | | | | | | |
| The medicine summary adverse events. | groups reported adverse ev | ents together. Pat | ients may have re | eported multiple | | | |
| Further information ab | out the medicine summary | | | | | | |
| Information on printing | search results | | | | | | |
| Sort by: Print version of this report | | | | | | | |
| Number of cases - hig | hest first | | V | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | |
| Pregnancy, puerperium and | Foetal death | 1 | 1 | 1 | | | |

Verifiable death –Female – 32 Foetal death also reported

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 639647 | 07/10/2021 | 32 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Foetal deathFoetal hypokinesiaRash pruritic |

we know the death reported was the 32 year old mother as we can filter for age (18 to 64) with BETA DAEN. However, there was also a foetal death reported

■ <u>5 medicines selected</u> between 08/10/2021 - 08/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Subarachnoid haemorrhage | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 640350 | 08/10/2021 | 45 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cerebrovascular accident Chest pain Dyspnoea Headache Subarachnoid haemorrhage |

■ <u>5 medicines selected</u> between 12/10/2021 - 12/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Number of cases - highest first

Sort by:

Print version of this report

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 641824 | 12/10/2021 | 74 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardiac arrest Fibrin D dimer increased Hypertension Thrombocytopenia |

■ 5 medicines selected between 13/10/2021 - 13/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summa | List of reports | | | |
|-----------------------------------|---|-------------------|--|--|
| Medicine summ | nary | | | |
| The medicine summ adverse events. | ary groups reported adverse ev | ents together. Pa | tients may have re | ported multiple |
| Further information | about the medicine summary | | | |
| Information on print | ing search results | | | |
| Sort by: | | | Print ve | rsion of this |
| Number of cases - I | nighest first | | ~ | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
| Cardiac disorders | Coronary artery disease | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 642780 | 13/10/2021 | 71 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Coronary artery disease |

■ 1 medicine selected between 13/10/2021 - 13/10/2021.

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Pulmonary embolism | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 642977 | 13/10/2021 | 30 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Pulmonary embolism |

■ 5 medicines selected between 14/10/2021 - 14/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

•

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Coronary artery disease | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 643592 | 14/10/2021 | 65 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Abdominal discomfort Coronary artery disease Cyanosis Lethargy Malaise Pallor |

■ 5 medicines selected between 14/10/2021 - 14/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|-------------------------|--------------|--------|--|--|
| 644148 | 14/10/2021 | 21 | M | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected Bexsero (Neisseria meningitidis Group B Factor H Binding Protein fusion protein; Neisseria meningitidis Group B Neisseria Adhesin A protein; Neisseria meningitidis Group B Neisseria Heparin Binding Antigen fusion protein; Neisseria meningitidis serogroup B outer membrane vesicles) - Not suspected | Cardiac arrest Concomitant disease aggravated Malaise Pulmonary hypertension Pyrexia |

■ <u>5 medicines selected</u> between 14/10/2021 - 14/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summary | List of reports | | | | | | | |
|---|---|-----------------|--|--|--|--|--|--|
| Medicine summa | ry | | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | | |
| Further information ab | out the medicine summary | | | | | | | |
| Information on printin | g search results | | | | | | | |
| Sort by: | | | | rsion of this | | | | |
| Number of cases - hig | hest first | | report | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | |
| Investigations | International normalised ratio abnormal | 1 | 1 | 1 | | | | |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 643809 | 14/10/2021 | 74 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation International normalised ratio abnormal |

■ 5 medicines selected between 15/10/2021 - 15/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

■ More information on the search results

| Medicine summa | List of reports | | | | | | | |
|-----------------------|--|--------------------|---|---|--|--|--|--|
| Medicine summary | | | | | | | | |
| The medicine summa | ary groups reported adverse ev | ents together. Pat | ients may have re | ported multiple | | | | |
| Further information | about the medicine summary | | | | | | | |
| Information on print | ing search results | | | | | | | |
| Sort by: | | | | rsion of this | | | | |
| Number of cases - h | nighest first | | report | | | | | |
| MedDRA | MedDRA reaction term | Number of | Number of | Number of | | | | |
| system organ class | Click on a term below to search the <u>MedlinePlus medical</u> <u>dictionary</u> . | cases | cases with a single suspected medicine | cases where death was a reported outcome | | | | |
| Cardiac disorders | Cardiac arrest | 2 | 2 | 2 | | | | |

1 - Verifiable death -Female -age 44 2 - Verifiable death -Male -age 56

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 644735 | 15/10/2021 | 44 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardiac arrest Dyspnoea Fibrin D dimer increased Pulmonary embolism Pyrexia Thrombocytopenia Thrombosis |
| 644868 | 15/10/2021 | 56 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cardiac arrest |

■ 1 medicine selected between 15/10/2021 - 15/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

| Medicine summa | <u>ry</u> | <u>List of reports</u> | | | | | | |
|--|-----------|------------------------|-------------|---|----------|---|--|--|
| Medicine summary | | | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | | |
| Further information a | about th | e medicine summ | <u>iary</u> | | | | | |
| Information on printi | ng sear | ch results | | | | | | |
| Sort by: | | | | | | | | |
| Number of cases - h | ighest f | irst | | | V | | | |
| MedDRA MedDRA reaction term Number of cases Number of cases with a dictionary. Number of cases with a cases with a suspected medicine Number of cases with a cases with a suspected medicine | | | | | | | | |
| Cardiac disorders | Муоса | rditis | | 2 | 2 | 1 | | |

Verifiable death -Female -age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 644718 | 15/10/2021 | - | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Myocarditis |

■ 1 medicine selected between 15/10/2021 - 15/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

List of reports

■ More information on the search results

Medicine summary

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Cardiac disorders | Palpitations | 3 | 2 | 1 |

 $\overline{}$

Verifiable death –Male –age 20

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 644353 | 15/10/2021 | 20 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | • <u>Palpitations</u> |

we know this is the case that had a death reported also because the other 2 cases had other reactions reported that were not associated with a death

■ <u>5 medicines selected</u> between 19/10/2021 - 19/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|---|-----------------|--|--|
| Infections and infestations | Pneumonia aspiration | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 647067 | 19/10/2021 | 84 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Ataxia Cerebrovascular accident Lethargy Pneumonia aspiration |

■ <u>5 medicines selected</u> between 19/10/2021 - 19/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Cerebral haemorrhage | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 646740 | 19/10/2021 | 83 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebral haemorrhage Headache Muscle spasms |

■ 5 medicines selected between 19/10/2021 - 19/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Gastrointestinal disorders | Gastrointestinal haemorrhage | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 647034 | 19/10/2021 | 65 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Basal ganglia haemorrhage Gastrointestinal haemorrhage Hypertension |

■ 5 medicines selected between 20/10/2021 - 20/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

Verifiable death –Female –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 647488 | 20/10/2021 | - | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

■ 5 medicines selected between 20/10/2021 - 20/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Brain herniation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 647663 | 20/10/2021 | 14 | F | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Brain herniation Brain injury Cardiac arrest Dizziness Headache Multiple organ dysfunction syndrome Nausea Pyrexia |

■ 5 medicines selected between 20/10/2021 - 20/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

disorders

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 647153 | 20/10/2021 | 63 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Fibrin D dimer increased Hypercapnia Respiratory failure Thrombocytopenia |

■ 5 medicines selected between 21/10/2021 - 21/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Myocardial infarction | 1 | 1 | 1 |

Verifiable death -Male -age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 648326 | 21/10/2021 | - | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | DyspnoeaMyocardial infarctionPneumonia |

■ <u>5 medicines selected</u> between 21/10/2021 - 21/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary List of

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac failure | 1 | 1 | 1 |

| <u>Case</u> number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|-----------------------|----------------------|--------------|--------|---|---|
| 648284 | 21/10/2021 | 76 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardiac failure Cardio-respiratory arrest Pulmonary embolism Thrombocytopenia |

■ 5 medicines selected between 21/10/2021 - 21/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

List of reports

■ More information on the search results

Medicine summary

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Haemorrhage intracranial | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 647972 | 21/10/2021 | 76 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Atrioventricular block Haemorrhage intracranial |

■ <u>5 medicines selected</u> between 21/10/2021 - 21/10/2021.

Selected medicines

| Trade name | Active ingredients | | |
|------------------------------|---------------------------------------|--|--|
| COMIRNATY COVID-19 vaccine | tozinameran | | |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) | | |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) | | |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) | | |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) | | |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summa | List of reports | | | | | | | |
|---------------------------------|--|--------------------|--|--|--|--|--|--|
| Medicine summary | | | | | | | | |
| The medicine summa | ary groups reported adverse ev | ents together. Pat | ients may have re | ported multiple | | | | |
| Further information | about the medicine summary | | | | | | | |
| Information on print | ing search results | | | | | | | |
| Sort by: | | | Print ve | rsion of this | | | | |
| Number of cases - h | nighest first | | V | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | |
| Cardiac disorders | Bradycardia | 1 | 1 | 1 | | | | |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 647812 | 21/10/2021 | 68 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Bradycardia Concomitant disease progression Hypotension Troponin abnormal |

■ <u>5 medicines selected</u> between 22/10/2021 - 22/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

 $\overline{}$

Number of cases - highest first

| MedDRA system org class | MedDRA rea Click on a term the MedlinePlus dictionary. | below to search | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|-------------------------------|---|-----------------|-----------------|--|--|
| Nervous sys disorders | tem <u>Cerebrovascu</u> | lar accident | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 648942 | 22/10/2021 | 54 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Amnesia Cerebrovascular accident Dysarthria Inappropriate schedule of product administration Myocardial fibrosis Tremor Vaccination error |

■ <u>5 medicines selected</u> between 22/10/2021 - 22/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Intracranial aneurysm | 1 | 1 | 1 |

Verifiable death –Female –age 54

Medicines reported as Case Report Age **Gender** MedDRA reaction number entry date (yrs) being taken terms Click on a term below to search the MedlinePlus medical dictionary. 22/10/2021 54 Intracranial 648930 COVID-19 Vaccine AstraZeneca aneurysm Subarachnoid (ChAdOx1-S (Viral vector)) - Suspected haemorrhage

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Injury, poisoning and

procedural

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

medical dictionary.

immunisation

Adverse event following

■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: $\overline{}$ Number of cases - highest first MedDRA system MedDRA reaction **Number of Number of** Number of organ class cases cases with a cases where death was a Click on a term below to single search the MedlinePlus suspected reported

medicine

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 648928 | 22/10/2021 | 59 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 24/10/2021 - 24/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: ${f 1}$

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Respiratory failure | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 649510 | 24/10/2021 | 66 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cardiac arrest Concomitant disease aggravated Dyspnoea Headache Myalgia Pyrexia Respiratory failure |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

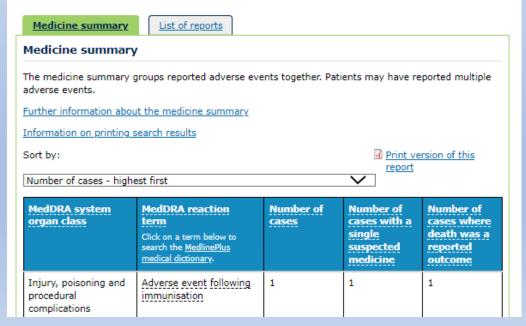
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 650265 | 25/10/2021 | 78 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Tradename not specified (Product not coded) - Not suspected Tradename not specified (aspirin) - Not suspected Tradename not specified (felodipine) - Not suspected Tradename not specified (felodipine) - Not suspected Tradename not specified (leflunomide) - Not suspected | Adverse event following immunisation Decreased appetite Dyspnoea Fatigue Pyrexia |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results

| 5 | ledDRA ystem organ lass | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|-------------------------------|---|-----------------|--|--|
| V | ascular disorders | Aortic dissection | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 649867 | 25/10/2021 | 62 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Aortic dissection Chest pain |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 651019 | 26/10/2021 | 86 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Concomitant disease progression |

■ <u>5 medicines selected</u> between 27/10/2021 - 27/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|-----------------------------|---|-----------------|--|--|
| Infections and infestations | Atypical pneumonia | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 651374 | 27/10/2021 | 43 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Atypical pneumonia Cardiac arrest Chest pain Dyspnoea Fibrin D dimer increased Liver function test abnormal Pyrexia |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

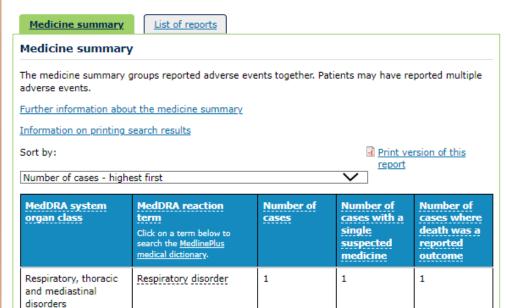
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 651140 | 27/10/2021 | 18 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Cardiac disorder Headache Pain in extremity Respiratory disorder |

■ <u>5 medicines selected</u> between 27/10/2021 - 27/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 0 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 651143 | 27/10/2021 | 77 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Concomitant disease progression Pyrexia |

Verifiable death -Male -age 70

Database of Adverse Event Notifications (DAEN) - medicines

Inclusion in DAEN - medicines does not mean that the adverse event has been confirmed or that it was caused by a medicine or vaccine.

| MedDRA system organ class | MedDRA reaction term | cases | single suspected | Cases where death was a reported outcome |
|-----------------------------|----------------------|-------|------------------|--|
| Infections and infestations | Pneumonia | 1 | 1 | 1 |

List of reports - (1 rows)

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Hover over the table to view exporting data and other options. Click on the dots to see more options. \rightarrow

| Case number ▼ | Report entry date | Age (years) | Gender | Medicines reported as being taken | MedDRA reaction terms |
|----------------------|-------------------|-------------|--------|---|-----------------------|
| 651672 | 27/10/2021 | 70 | Male | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | • Pneumonia |

Age (years)

- Select all
- 18 to 64
- ✓ 65 and above
- Unknown

Gender

- Select all
- Male

■ <u>5 medicines selected</u> between 28/10/2021 - 28/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

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Number of cases - highest first

Sort by:

Print version of this report

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Musculoskeletal and connective tissue disorders | Myositis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 652299 | 28/10/2021 | 76 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Autoimmune hepatitis Hepatic failure Hepatitis Multiple organ dysfunction syndrome Myositis Pneumonitis |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Investigations | Haemoglobin decreased | 1 | 0 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 651938 | 28/10/2021 | 72 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Acute kidney injury Concomitant disease aggravated C-reactive protein increased Fibrin D dimer increased Haemoglobin decreased Hypotension Hypothermia Pulmonary embolism Red blood cell count decreased SARS-CoV-2 antibody test positive Thrombocytopenia |

■ <u>5 medicines selected</u> between 28/10/2021 - 28/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

Sort by:

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Number of cases - highest first

Print version of this report

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Myocardial infarction | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 652222 | 28/10/2021 | 45 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Chest discomfort Electrocardiogram Malaise Myocardial infarction Pulmonary embolism |

■ <u>5 medicines selected</u> between 29/10/2021 - 29/10/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 652908 | 29/10/2021 | 69 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Cardiac arrest |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

organ class

conditions

General disorders and

administration site

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summary | <u>List of reports</u> | | | | |
|---|------------------------|-------------|--------------------|----------------|-------------------|
| Medicine summary | | | | | |
| The medicine summary gro adverse events. | oups reported adve | rse ever | nts together. Pati | ients may have | reported multiple |
| Further information about | the medicine summ | <u>nary</u> | | | |
| Information on printing sea | arch results | | | | |
| Sort by: | | | | Print v | rersion of this |
| Number of cases - highest | first | | | ~ | |
| MedDRA system | MedDRA reaction | | Number of | Number of | Number of |

Click on a term below to search the MedlinePlus

Concomitant disease

medical dictionary.

progression

cases

cases with a

suspected

medicine

single

cases where death was a

reported

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 653923 | 01/11/2021 | 54 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Concomitant disease progression |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 2 | 2 | 2 |

1- Verifiable death –Female –age 67 1- Verifiable death –Female –age 90

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 654671 | 02/11/2021 | 67 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Adverse event following immunisation |
| 654855 | 02/11/2021 | 90 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

 $\overline{}$

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Cardiac disorders | Myocardial ischaemia | 2 | 2 | 2 |

1 - Verifiable death –Male –age 531 - Verifiable death –Male –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 654681 | 02/11/2021 | 53 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Arteriosclerosis coronary artery Dyspnoea Malaise Myocardial ischaemia |
| 654822 | 02/11/2021 | - | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Epistaxis Myocardial ischaemia Thrombosis |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac failure congestive | 2 | 2 | 2 |

1- Verifiable death –Female –age 66 1- Verifiable death –Female –age 54

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 654653 | 02/11/2021 | 66 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardiac failure congestive Hypertensive heart disease |
| 654668 | 02/11/2021 | 54 | F | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | Cardiac failure congestive Hypertensive heart disease |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Cerebral haemorrhage | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 654651 | 02/11/2021 | 71 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | <u>Cerebral</u> haemorrhage |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 654798 | 02/11/2021 | 90 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease progression |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Cerebellar infarction | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 655005 | 03/11/2021 | 58 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Back pain Blood fibrinogen increased Cerebellar infarction Cerebral infarction Chest pain Endocarditis Fibrin D dimer increased Headache Hyperhidrosis Lymphadenopathy Multiple organ dysfunction syndrome Pyrexia Splenomegaly Staphylococcal sepsis Thrombocytopenia Troponin increased Vomiting |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Musculoskeletal and

connective tissue disorders

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

More information on the search results

| Medicine summary | <u>List of reports</u> | | | | | | | |
|---|------------------------|-----------------|------------------------|-----------------------|--|--|--|--|
| Medicine summary | | | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | | |
| Further information about the medicine summary | | | | | | | | |
| Information on printing s | earch results | | | | | | | |
| Sort by: | | | | | | | | |
| Number of cases - highest first | | | | | | | | |
| MedDRA system organ class | MedDRA reaction term | Number of cases | Number of cases with a | Number of cases where | | | | |

Click on a term below to search the <u>MedlinePlus</u> medical dictionary.

Costochondritis

death was a

reported

outcome

single

suspected medicine

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 655018 | 03/11/2021 | 30 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Agonal respiration Chest pain Costochondritis Myopericarditis Troponin T |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single <u>suspected</u> medicine: 1

Number of cases where <u>death</u> was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Vascular stent thrombosis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 655075 | 03/11/2021 | 57 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Vascular stent thrombosis |

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

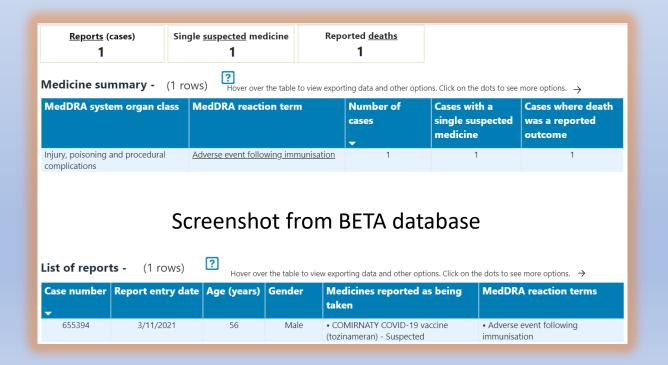
Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report Number of cases - highest first $\overline{}$ MedDRA reaction MedDRA system Number of **Number of** Number of cases with a cases where organ class cases single death was a Click on a term below to search the MedlinePlus suspected reported medical dictionary. medicine outcome Adverse event following Injury, poisoning and procedural immunisation complications

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 655394 | 03/11/2021 | 56 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |



Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|-----------------------------|--|-----------------|--|--|
| Infections and infestations | Encephalitis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 655686 | 04/11/2021 | 75 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Encephalitis |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single <u>suspected</u> medicine: 1

Number of cases where <u>death</u> was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 658313 | 04/11/2021 | 95 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebrovascular accident |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

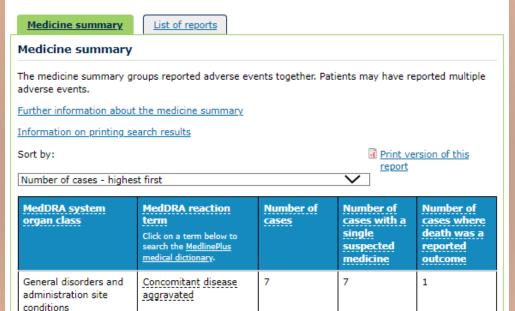
The results are shown in two tabs.

Number of reports (cases): 7

Number of cases with a single suspected medicine: 7

Number of cases where death was a reported outcome: 1

More information on the search results



Verifiable death –Female –age 64

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 658344 | 04/11/2021 | 64 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Chest pain Concomitant disease aggravated Myocarditis Palpitations |

We know this was the case that also had a death reported because of their other reactions having a death reported also

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------------|--|-----------------|--|--|
| Surgical and medical procedures | Subdural haematoma evacuation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 658641 | 05/11/2021 | 82 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Chest pain Dyspnoea Extradural haematoma Extradural haematoma evacuation Fibrin D dimer increased Subdural haematoma Subdural haematoma evacuation Thrombocytopenia |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

 $\overline{\mathsf{v}}$

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

Verifiable death -Male -age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 659968 | 05/11/2021 | - | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

complications

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

List of reports Medicine summary Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: $\overline{}$ Number of cases - highest first MedDRA system MedDRA reaction **Number of** Number of Number of organ class term cases cases with a cases where single death was a Click on a term below to search the MedlinePlus suspected reported medical dictionary. medicine outcome Injury, poisoning and Adverse event following procedural immunisation

Verifiable death -Male -age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 660605 | 08/11/2021 | - | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 660545 | 08/11/2021 | 64 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Acute pulmonary oedema Cardiac failure Ischaemic stroke |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first



| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 661396 | 09/11/2021 | 84 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

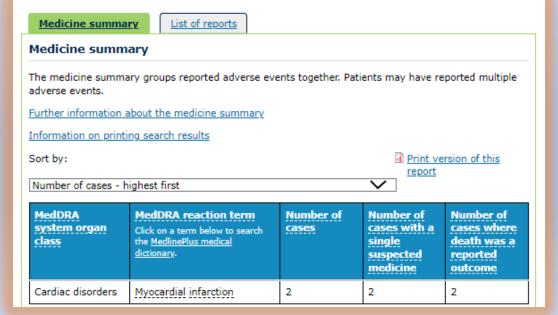
The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

More information on the search results



1- Verifiable death –Female –age 77

2- Verifiable death -Female -age 69

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 662057 | 10/11/2021 | 77 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Myocardial infarction |
| 662528 | 10/11/2021 | 69 | F | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | Myocardial infarction |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|---|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Respiratory failure | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 662238 | 10/11/2021 | 49 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease aggravated Pneumonia Respiratory failure |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

$\underline{\text{Medicine summary}}$

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 0 | 1 |

| Case numl | | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|--------------|----|----------------------|--------------|--------|---|--|
| 66194 | 17 | 10/11/2021 | 74 | М | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected Influenza Vaccine (TNS) (Influenza virus haemagglutinin) - Suspected | Cardiac arrestChest painDemyelinationMyopathy |

■ 5 medicines selected between 12/11/2021 - 12/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Carotid artery dissection | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 663471 | 12/11/2021 | 39 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Carotid artery dissection Cerebrovascular accident Haemorrhage intracranial Migraine Neck pain Sensory disturbance Vasculitis Visual impairment |

■ <u>5 medicines selected</u> between 14/11/2021 - 14/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

■ More information on the search results

<u>Medicine summary</u>

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------------|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal | Pulmonary oedema | 1 | 0 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 664116 | 14/11/2021 | 76 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected FluQuadri Vaccine (Influenza virus haemagglutinin) - Suspected | Deep vein thrombosis Fibrin D dimer increased Gastrointestinal haemorrhage Haemoglobin decreased Pleural effusion Pulmonary embolism Pulmonary oedema Thrombocytopenia |

■ <u>5 medicines selected</u> between 15/11/2021 - 15/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summa | <u>List of reports</u> | | | |
|---------------------------------|---|--------------------|--|--|
| Medicine summ | ary | | | |
| adverse events. | ary groups reported adverse ev | ents together. Pat | ients may have re | ported multiple |
| Information on print | | | | |
| Information on print | ing search results | | | |
| Sort by: | | | | rsion of this |
| Number of cases - h | nighest first | | report | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
| Cardiac disorders | Myocardial ischaemia | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 664459 | 15/11/2021 | 87 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Myocardial ischaemia |

■ 5 medicines selected between 15/11/2021 - 15/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|-----------------------------|--|-----------------|--|--|
| Infections and infestations | Cellulitis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 664467 | 15/11/2021 | 68 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cellulitis Concomitant disease aggravated COVID-19 |

■ <u>5 medicines selected</u> between 16/11/2021 - 16/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiogenic shock | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 665298 | 16/11/2021 | 54 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cardiogenic shock Concomitant disease aggravated |

■ <u>5 medicines selected</u> between 16/11/2021 - 16/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Haemoptysis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 665580 | 16/11/2021 | 76 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Chest pain Cough Dyspnoea Haematemesis Haemoptysis Troponin increased |

■ <u>5 medicines selected</u> between 17/11/2021 - 17/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

| Med | icine | sumr | nar |
|-----|-------|------|-----|
| | | | |

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Coronary artery thrombosis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 666320 | 17/11/2021 | 29 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Coronary artery thrombosis |

■ <u>5 medicines selected</u> between 17/11/2021 - 17/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

$\underline{\mathsf{Medicine}\;\mathsf{summary}}$

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------|--|-----------------|--|--|
| Investigations | Troponin abnormal | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 666237 | 17/11/2021 | 53 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Cardiac arrest Pericardial effusion Troponin abnormal |

■ <u>5 medicines selected</u> between 17/11/2021 - 17/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single $\underline{\text{suspected}}$ medicine: $\boldsymbol{1}$

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

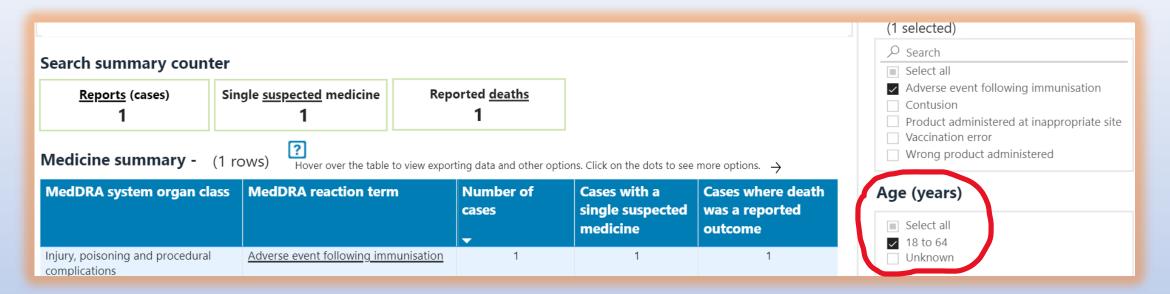
Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------|--|-----------------|--|--|
| Investigations | SARS-CoV-2 antibody test positive | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 666439 | 17/11/2021 | 51 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Diarrhoea Pneumonia SARS-CoV-2 antibody test positive |

Verifiable death –Male –age 35



| List of reports | s - (1 rows) | ? Hover ove | r the table to view | w exporting data and other options. Click on th | e dots to see more options. \rightarrow |
|----------------------|---------------------|-------------|---------------------|---|--|
| Case number ▼ | Report entry date | Age (years) | Gender | Medicines reported as being taken | MedDRA reaction terms |
| 666360 | 17/11/2021 | 35 | Male | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected Trade name not specified (amisulpride) - Not suspected | Adverse event following immunisation Myocarditis |

We know this case was the case that resulted in death as it was in the age range of 18 to 64 based on the BETA search, the other case had no age listed

■ 5 medicines selected between 17/11/2021 - 17/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

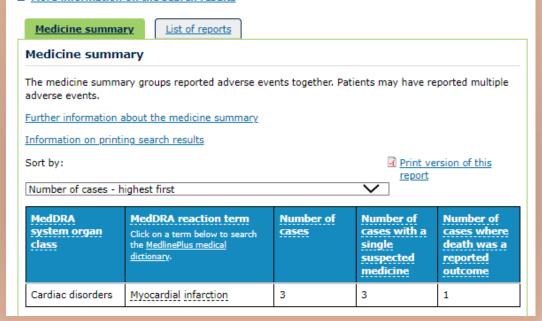
The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 1

■ More information on the search results

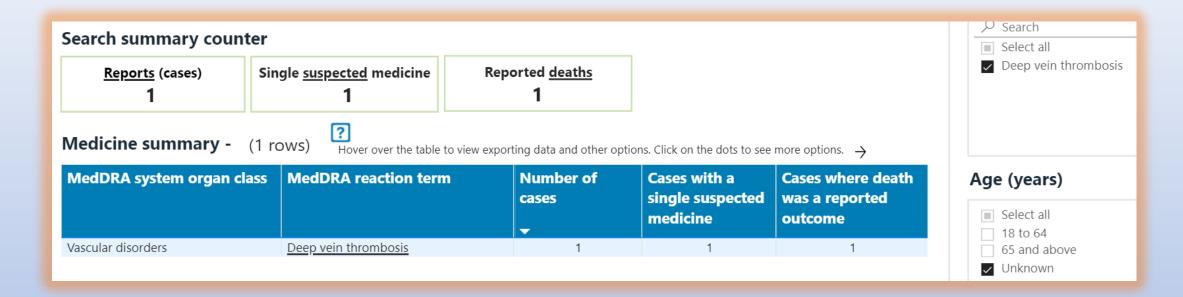


Verifiable death -Male -age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 666513 | 17/11/2021 | - | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Myocardial infarction |

We know this is the case that had a death reported as the other 2 cases had other reactions not associated with a death

Verifiable death –Male –age undisclosed



| List of report | ts - (1 rows) | ? Hover ove | r the table to viev | w exporting data and other options. Click on th | e dots to see more options. 🗡 |
|----------------------|----------------------|-------------|---------------------|---|-------------------------------|
| Case number ▼ | Report entry date | Age (years) | Gender | Medicines reported as being taken | MedDRA reaction terms |
| 666299 | 17/11/2021 | - | Male | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Deep vein thrombosis |

■ <u>5 medicines selected</u> between 18/11/2021 - 18/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 667316 | 18/11/2021 | 66 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease progression |

■ 5 medicines selected between 19/11/2021 - 19/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

and mediastinal disorders

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: <u>report</u> Number of cases - highest first $\overline{}$ MedDRA system **Number of** MedDRA reaction **Number of Number of** organ class cases cases with a cases where death was a single Click on a term below to search the MedlinePlus suspected reported medical dictionary. medicine outcome Respiratory, thoracic Respiratory arrest

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 667940 | 19/11/2021 | 77 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Arthralgia Concomitant disease progression Haematuria Myalgia Respiratory arrest |

■ <u>5 medicines selected</u> between 19/11/2021 - 19/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| | MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|-----|---------------------------------|--|-----------------|--|--|
| - 1 | Nervous system disorders | Cerebral haemorrhage | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 668139 | 19/11/2021 | 82 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebral haemorrhage Cerebrovascular accident Confusional state Headache Rash |

■ 1 medicine selected between 19/11/2021 - 19/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first



| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease aggravated | 2 | 1 | 1 |

Verifiable death -Male -age 80

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 667978 | 19/11/2021 | 80 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease aggravated Cough Dyspnoea Pyrexia |

we know this is the case that had a death reported also as the other reactions also had a death associated with this case

■ <u>5 medicines selected</u> between 20/11/2021 - 20/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 668656 | 20/11/2021 | 68 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Cardiac arrest Fatique Myocardial ischaemia Tachycardia |

■ 5 medicines selected between 23/11/2021 - 23/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------|--|-----------------|--|--|
| Investigations | Weight increased | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 669674 | 23/11/2021 | 93 | F | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | Electrocardiogram abnormal Malaise Obstructive shock Oedema peripheral Organ failure Pleural effusion Pulmonary embolism Rectal haemorrhage Weight increased |

■ 5 medicines selected between 23/11/2021 - 23/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Arteriosclerosis coronary artery | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 670217 | 23/11/2021 | 64 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Arteriosclerosis coronary artery |

■ <u>5 medicines selected</u> between 23/11/2021 - 23/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single <u>suspected</u> medicine: **0**Number of cases where <u>death</u> was a reported outcome: **1**

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Cardiac disorders | Coronary artery disease | 1 | 0 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 669765 | 23/11/2021 | 37 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Coronary artery disease |

■ 5 medicines selected between 24/11/2021 - 24/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Cardiac disorders

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

Cardiac arrest

■ More information on the search results

| Medicine summa | List of reports | | | | | | | | |
|------------------------------------|---|-----------------|--|--|--|--|--|--|--|
| Medicine summ | ary | | | | | | | | |
| The medicine summa adverse events. | The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | | |
| Further information a | about the medicine summary | | | | | | | | |
| Information on printi | ng search results | | | | | | | | |
| Sort by: | | | | rsion of this | | | | | |
| Number of cases - h | ighest first | | report | | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | | |

Verifiable death -Male -age 79

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 670921 | 24/11/2021 | 79 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Cardiac arrest |

we know this is the case that also reported a death as the other case had another reaction that was not associated with a death

■ <u>5 medicines selected</u> between 25/11/2021 - 25/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Investigations | Oxygen saturation decreased | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 671307 | 25/11/2021 | 60 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Abdominal pain Dyspnoea Fibrin D dimer increased Hepatic failure Oxygen saturation decreased Peripheral swelling Pulmonary embolism Renal failure Renal infarct Respiratory failure Splenic infarction Thrombocytopenia Thrombosis Troponin increased |

■ <u>5 medicines selected</u> between 26/11/2021 - 26/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|---|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Pleural effusion | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 672528 | 26/11/2021 | 94 | F | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Chest pain Cough Pleural effusion |

■ <u>5 medicines selected</u> between 27/11/2021 - 27/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Bradycardia | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 672578 | 27/11/2021 | 75 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Bradycardia Bundle branch block right Cardiomegaly Cyanosis Deep vein thrombosis Fibrin D dimer increased Hypotension Hypoxia Pulmonary embolism Respiratory distress Syncope Tachycardia Troponin I increased |

■ 5 medicines selected between 28/11/2021 - 28/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 672776 | 28/11/2021 | 65 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Ventolin (salbutamol) - Not suspected | Cerebrovascular accident |

■ <u>5 medicines selected</u> between 29/11/2021 - 29/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summary | | <u>List of reports</u> |
|------------------|--|------------------------|
|------------------|--|------------------------|

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Gastrointestinal disorders | Haematemesis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 673255 | 29/11/2021 | 58 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | EpistaxisHaematemesisHaemorrhage |

■ <u>5 medicines selected</u> between 29/11/2021 - 29/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Myocardial ischaemia | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 673150 | 29/11/2021 | 52 | М | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Myocardial ischaemia |

■ <u>5 medicines selected</u> between 29/11/2021 - 29/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

Infections and

infestations

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

Pneumonia

■ More information on the search results

Madicine summany List of reports

| Medicine Summar | List of reports | | | | | |
|-------------------------------------|---|--------------------|--|--|--|--|
| Medicine summa | ary | | | | | |
| The medicine summar adverse events. | ry groups reported adverse eve | nts together. Pati | ents may have re | ported multiple | | |
| Further information a | bout the medicine summary | | | | | |
| Information on printing | ng search results | | | | | |
| Sort by: | Sort by: | | | | | |
| Number of cases - hi | ghest first | | ~ | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | |

Verifiable death –Male –age 72

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 673298 | 29/11/2021 | 72 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | • Pneumonia |

we know this was the case that had a death reported also as the other case had other reactions reported that were not associated with a death

■ 1 medicine selected between 29/11/2021 - 29/11/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------|---------------------------------------|
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

<u>Medicine summary</u>

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Myocardial infarction | 1 | 1 | 1 |

Verifiable death -Male -age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 673114 | 29/11/2021 | - | М | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | Myocardial infarction |

■ 5 medicines selected between 01/12/2021 - 01/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

List of reports

■ More information on the search results

Medicine summary Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Number of cases - highest first

Print version of this report

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Subarachnoid haemorrhage | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 675554 | 01/12/2021 | 80 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected Tradename not specified (apixaban) - Not suspected | Cardiac arrest Subarachnoid haemorrhage |

■ <u>5 medicines selected</u> between 01/12/2021 - 01/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 674876 | 01/12/2021 | 78 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease progression |

■ 5 medicines selected between 02/12/2021 - 02/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

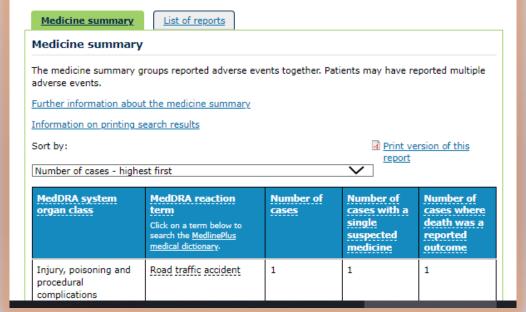
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 676189 | 02/12/2021 | 33 | М | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Road traffic accident Syncope |

■ <u>5 medicines selected</u> between 05/12/2021 - 05/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

organ class

procedural

complications

Injury, poisoning and

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

term

Click on a term below to

Adverse event following

search the MedlinePlus medical dictionary.

immunisation

■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report $\overline{}$ Number of cases - highest first MedDRA system MedDRA reaction **Number of Number of** Number of cases where

cases

cases with a

suspected

medicine

single

death was a

reported

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 677285 | 05/12/2021 | 63 | М | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Adverse event following immunisation Constipation Cough |

■ 5 medicines selected between 06/12/2021 - 06/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 677502 | 06/12/2021 | 88 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cerebrovascular accident |

■ <u>5 medicines selected</u> between 06/12/2021 - 06/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 1 | 1 |

Verifiable death -Female -age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 677821 | 06/12/2021 | - | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Blood urine present Concomitant disease progression Extensive swelling of vaccinated limb |

■ 5 medicines selected between 08/12/2021 - 08/12/2021.

Selected medicines

| Trade name | Active ingredients | | |
|------------------------------|---------------------------------------|--|--|
| COMIRNATY COVID-19 vaccine | tozinameran | | |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) | | |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) | | |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) | | |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) | | |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 2 | 2 | 2 |

1 - Verifiable death –Male –age 772 - Verifiable death –Female –age 77

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 679242 | 08/12/2021 | 77 | М | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Acute myocardial infarction Cardiac arrest Multiple organ dysfunction syndrome |
| 679387 | 08/12/2021 | 77 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Acute myocardial infarction Cardiac arrest Electrocardiogram abnormal Hypocalcaemia Hypoglycaemia Hypokalaemia |

■ <u>5 medicines selected</u> between 09/12/2021 - 09/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summa | List of reports | | | |
|-----------------------------------|---|--------------------|--|--|
| Medicine summ | nary | | | |
| The medicine summ adverse events. | ary groups reported adverse ev | ents together. Pat | ients may have re | ported multiple |
| Further information | about the medicine summary | | | |
| Information on print | ing search results | | | |
| Sort by: | | | | rsion of this |
| Number of cases - I | nighest first | | report | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 679513 | 09/12/2021 | 72 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardiac arrestChest painHeadacheLimb discomfortPyrexia |

■ 1 medicine selected between 09/12/2021 - 09/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|---|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 680111 | 09/12/2021 | 63 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 10/12/2021 - 10/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the <u>MedlinePlus</u> medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|---|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Respiratory failure | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 680418 | 10/12/2021 | 77 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Concomitant disease progression Pneumonia Respiratory failure |

■ <u>5 medicines selected</u> between 11/12/2021 - 11/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Cerebral infarction | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 680694 | 11/12/2021 | 94 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebellar infarction Cerebral infarction Pulmonary embolism |

■ <u>5 medicines selected</u> between 11/12/2021 - 11/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Cerebral artery thrombosis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 680695 | 11/12/2021 | 72 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebral artery thrombosis Metastases to liver Pancreatic carcinoma |

■ 5 medicines selected between 13/12/2021 - 13/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

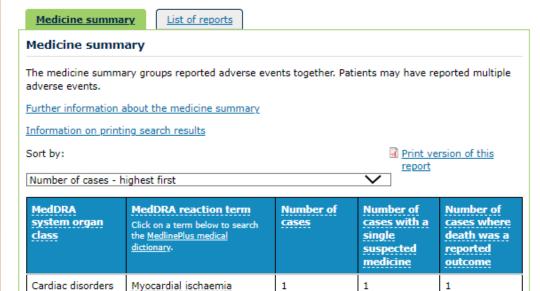
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 681158 | 13/12/2021 | 77 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Myocardial ischaemia |

■ 5 medicines selected between 13/12/2021 - 13/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Sort by: Print version of this report Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Pericardial haemorrhage | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 681338 | 13/12/2021 | 61 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Aortic dissection rupture Pericardial haemorrhage |

■ 5 medicines selected between 13/12/2021 - 13/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

MedDRA

class

system organ

Cardiac disorders

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

MedDRA reaction term

Click on a term below to search the MedlinePlus medical

dictionary.

Cardiomegaly

More information on the search results

Medicine summary Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Sort by: Print version of this report Number of cases - highest first

Number of

cases

Number of

suspected

medicine

single

cases with a

Number of cases where

death was a

reported

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 681341 | 13/12/2021 | 54 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | • <u>Cardiomegaly</u> |

■ <u>5 medicines selected</u> between 14/12/2021 - 14/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summa | List of reports | | | | | | | |
|--|----------------------------|---|----------|---------------|--|--|--|--|
| Medicine summary | | | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | | |
| Further information | about the medicine summary | | | | | | | |
| Information on print | ing search results | | | | | | | |
| Sort by: | | | Print ve | rsion of this | | | | |
| Number of cases - h | nighest first | | <u> </u> | | | | | |
| MedDRA MedDRA reaction term System organ Click on a term below to search the MedlinePlus medical dictionary. Number of Cases with a cases where death was a suspected medicine outcome | | | | | | | | |
| Vascular disorders | Internal haemorrhage | 1 | 1 | 1 | | | | |

| Cas nur | se mber | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|------------|------------|----------------------|--------------|--------|---|---|
| 681 | .656 | 14/12/2021 | 90 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Deep vein thrombosis Internal haemorrhage Migraine Oedema peripheral Pulmonary embolism |

■ <u>5 medicines selected</u> between 15/12/2021 - 15/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Cerebral infarction | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 682377 | 15/12/2021 | 78 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected | Cerebral infarction Diarrhoea Guillain-Barre syndrome |

■ 5 medicines selected between 15/12/2021 - 15/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | <u>Fall</u> | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 682908 | 15/12/2021 | 89 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation Cerebrovascular accident Fall |

5 medicines selected between 15/12/2021 - 15/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|---|-----------------|--|--|
| Blood and lymphatic system disorders | Thrombocytopenia | 2 | 2 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 682142 | 15/12/2021 | 74 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | CardiomyopathyContusionThrombocytopeniaVisual impairment |

■ 1 medicine selected between 15/12/2021 - 15/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 2

More information on the search results

Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Sort by: Print version of this report Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 3 | 3 | 2 |

Verifiable death –Male –age 53

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 682371 | 15/12/2021 | 53 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

We know this case had a death reported also (89/F had a death reported also) because we searched using the BETA site and were able to filter for age between 18 to 64 which showed a death was reported for this sole case in this age category

■ <u>5 medicines selected</u> between 17/12/2021 - 17/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Cardiac disorders

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

Myocardial ischaemia

■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report \checkmark Number of cases - highest first MedDRA **Number of Number of Number of** MedDRA reaction term system organ cases with a cases where cases Click on a term below to search class the MedlinePlus medical single death was a dictionary. reported suspected medicine outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 683978 | 17/12/2021 | 70 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Acquired haemophilia Myocardial ischaemia Renal failure Respiratory failure Sepsis |

■ 5 medicines selected between 17/12/2021 - 17/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

More information on the search results

$\underline{\mathsf{Medicine}\;\mathsf{summary}}$

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|-----------------------------|---|-----------------|--|--|
| Infections and infestations | Pneumonia | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 683823 | 17/12/2021 | 90 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | General physical health deterioration Pneumonia Sepsis |

■ 5 medicines selected between 20/12/2021 - 20/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 684632 | 20/12/2021 | 80 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardiac arrest Concomitant disease aggravated Decreased appetite Echocardiogram Endocarditis Fibrin D dimer increased Lethargy Melaena Thrombocytopenia Vomiting |

■ <u>5 medicines selected</u> between 20/12/2021 - 20/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 2 | 2 | 1 |

Verifiable death –sex unknown age unknown

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 684616 | 20/12/2021 | - | - | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cerebrovascular accident |

■ 5 medicines selected between 21/12/2021 - 21/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

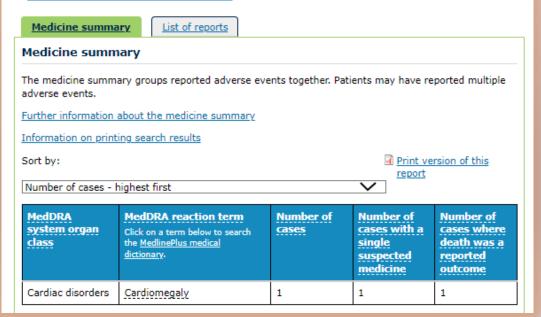
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 685337 | 21/12/2021 | 23 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cardiomegaly Malaise Personality change |

■ <u>5 medicines selected</u> between 22/12/2021 - 22/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 0 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 686483 | 22/12/2021 | 48 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Concomitant disease progression Dyspnoea Hallucination |

■ 5 medicines selected between 23/12/2021 - 23/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 686938 | 23/12/2021 | 90 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Deep vein thrombosis Internal haemorrhage Migraine Oedema peripheral Petechiae Pulmonary embolism |

■ 5 medicines selected between 23/12/2021 - 23/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Myocardial infarction | 2 | 2 | 1 |

Verifiable death -Female -age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 687085 | 23/12/2021 | - | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Myocardial infarction |

We know this is the case that had a death reported also because we could use filter 'age unknown' in BETA DAEN to confirm

■ 5 medicines selected between 25/12/2021 - 25/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 687442 | 25/12/2021 | 90 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cerebrovascular accident Concomitant disease progression Gastrointestinal haemorrhage Herpes zoster Malaise Myalgia Pancytopenia Sepsis |

■ <u>5 medicines selected</u> between 27/12/2021 - 27/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------|--|-----------------|--|--|
| Investigations | Blood lactic acid | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 687834 | 27/12/2021 | 44 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Blood lactic acid C-reactive protein increased Influenza like illness Myocarditis Parvovirus B19 test positive pH body fluid Pyrexia Syncope Thrombocytopenia Troponin I Ventricular fibrillation |

■ 5 medicines selected between 27/12/2021 - 27/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

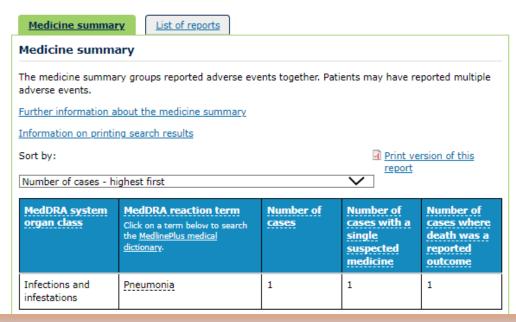
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 687718 | 27/12/2021 | 83 | М | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Confusional stateInjection site painPneumonia |

■ 5 medicines selected between 29/12/2021 - 29/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Cerebral infarction | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 688238 | 29/12/2021 | 72 | M | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cerebral infarction Cerebrovascular accident Coma scale Depressed level of consciousness Dysarthria Electrocardiogram Facial paralysis Hemiparesis Loss of consciousness Thrombosis |

■ 5 medicines selected between 30/12/2021 - 30/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 3

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 3 | 3 | 3 |

- 1- Verifiable death –Female –age 70
- 1- Verifiable death -Male -undisclosed
- 1- Verifiable death -Male -undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 688431 | 30/12/2021 | 70 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation Malaise |
| 688521 | 30/12/2021 | - | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Adverse event following immunisation |
| 688526 | 30/12/2021 | - | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 30/12/2021 - 30/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 688346 | 30/12/2021 | 86 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cerebrovascular accident Confusional state Dysphagia Hypertension |

■ <u>5 medicines selected</u> between 31/12/2021 - 31/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Cerebral infarction | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 688848 | 31/12/2021 | 68 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Cardiac arrest Cerebral infarction Multiple organ dysfunction syndrome |

■ 5 medicines selected between 31/12/2021 - 31/12/2021.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|---|-----------------|--|--|
| Investigations | C-reactive protein increased | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 688847 | 31/12/2021 | 86 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Abdominal pain C-reactive protein increased Delirium Fall Haemorrhage intracranial Urinary tract infection |

■ 5 medicines selected between 04/01/2022 - 04/01/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Number of cases - highest first

Sort by:

Print version of this report

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 689418 | 04/01/2022 | 92 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cardiac arrest Concomitant disease aggravated Infarction Respiratory arrest |

■ 5 medicines selected between 05/01/2022 - 05/01/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

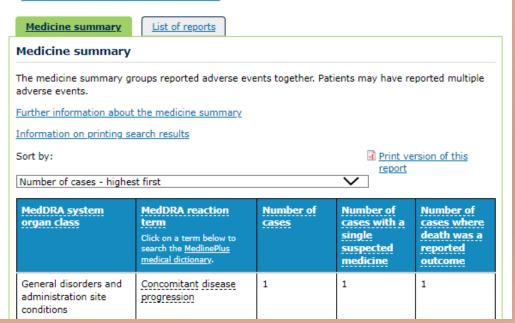
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 689732 | 05/01/2022 | 90 | F | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | Concomitant disease progression |

■ <u>5 medicines selected</u> between 06/01/2022 - 06/01/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single $\underline{\text{suspected}}$ medicine: $\mathbf{1}$

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

<u>Medicine summary</u>

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

 $\overline{}$

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Myocardial ischaemia | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 690477 | 06/01/2022 | 58 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Myocardial ischaemia |

■ 5 medicines selected between 09/01/2022 - 09/01/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Cardiac disorders

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

Cardiac arrest

More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: <u>report</u> Number of cases - highest first $\overline{}$ **Number of** MedDRA MedDRA reaction term **Number of Number of** system organ cases with a cases where cases Click on a term below to search class the MedlinePlus medical death was a single dictionary. suspected reported medicine outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 691465 | 09/01/2022 | 90 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Acute myocardial infarction Cardiac arrest Cardiogenic shock |

■ <u>5 medicines selected</u> between 10/01/2022 - 10/01/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

 $\overline{}$

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Acute pulmonary oedema | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 692021 | 10/01/2022 | 85 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Acute pulmonary oedema Concomitant disease progression |

■ 5 medicines selected between 10/01/2022 - 10/01/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

List of reports

More information on the search results

Medicine summary

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiomegaly | 1 | 0 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 692010 | 10/01/2022 | 53 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cardiomegaly Chest discomfort Chest pain Dyspnoea Pulmonary embolism |

■ <u>5 medicines selected</u> between 15/01/2022 - 15/01/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 695048 | 15/01/2022 | 15 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation Head banging |

■ 5 medicines selected between 16/01/2022 - 16/01/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 0 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 695164 | 16/01/2022 | 62 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Suspected Nexium (esomeprazole) Suspected | Concomitant disease progression Injection site pain Pain Vomiting |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 695644 | 17/01/2022 | 84 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease progression |

■ 5 medicines selected between 19/01/2022 - 19/01/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 697282 | 19/01/2022 | 81 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Myocardial ischaemia |

■ 5 medicines selected between 21/01/2022 - 21/01/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 698967 | 21/01/2022 | 73 | M | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Chest pain Concomitant disease progression Dyspnoea Gastrooesophageal reflux disease Malaise Nausea |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Myocardial infarction | 3 | 3 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 698345 | 21/01/2022 | 95 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Not suspected | Myocardial infarction Vaccination failure |

■ 5 medicines selected between 24/01/2022 - 24/01/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Respiratory failure | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 699744 | 24/01/2022 | 75 | М | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Not suspected | Concomitant disease progression COVID-19 Respiratory failure SARS-CoV-2 test positive Vaccination failure |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 701551 | 27/01/2022 | 89 | M | COMIRNATY COVID-19 vaccine (tozinameran) Suspected Tradename not specified (lercanidipine hydrochloride) - Not suspected Tradename not specified (pantoprazole) - Not suspected Tradename not specified (simvastatin) Not suspected Tradename not specified (telmisartan) Not suspected Metformin (metformin hydrochloride) - Not suspected Xarelto (rivaroxaban) - Not suspected | Cardiogenic shock Concomitant disease progression Gastric volvulus Intestinal ischaemia Multiple organ dysfunction syndrome Pneumonia |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

system organ

Cardiac disorders

class

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

Click on a term below to search

the MedlinePlus medical

Myocardial ischaemia

dictionary.

■ More information on the search results

Medicine summary List of reports **Medicine summary** The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report Number of cases - highest first $\overline{\mathsf{v}}$ MedDRA Number of **Number of** MedDRA reaction term **Number of**

cases

cases with a

single suspected

medicine

cases where

death was a

reported

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 703008 | 31/01/2022 | 81 | М | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Not suspected | Hypertensive heart disease Myocardial ischaemia |

■ 5 medicines selected between 31/01/2022 - 31/01/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Brain oedema | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 703118 | 31/01/2022 | 49 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Atrial fibrillation Brain oedema Cerebrovascular accident |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Fall | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 703511 | 31/01/2022 | 75 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Not suspected | Dyspnoea Fall Hyperhidrosis Loss of consciousness Respiratory arrest |

■ 5 medicines selected between 31/01/2022 - 31/01/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: ${f 1}$

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Atrial thrombosis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 703066 | 31/01/2022 | 72 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Atrial thrombosis |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single $\underline{\text{suspected}}$ medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\boldsymbol{1}$

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Arteriosclerosis coronary artery | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 703642 | 01/02/2022 | 72 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Arteriosclerosis coronary artery |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

More information on the search results



Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Number of cases - highest first

| | MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | |
|--|--|--|-----------------|--|--|--|--|--|
| | Injury, poisoning and procedural complications | Adverse event following immunisation | 2 | 2 | 1 | | | |

Print version of this

Verifiable death –Female –age 44

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 704505 | 02/02/2022 | 44 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

we know this is the case that had a death reported also because the other case had other reactions reported that were not associated with a death

■ 5 medicines selected between 10/02/2022 - 10/02/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 2 | 2 | 1 |

Verifiable death –Female –age 90

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 708611 | 10/02/2022 | 90 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cerebrovascular accident |

we know this is the case that had a death reported also because the other case had another reaction reported that was not associated with a death

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 709371 | 12/02/2022 | 72 | M | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cardiac arrest Concomitant disease aggravated C-reactive protein increased Dyspnoea Oedema peripheral Orthopnoea Skin ulcer Troponin increased |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

disorders

The results are shown in two tabs.

Number of reports (cases): 6

Number of cases with a single suspected medicine: 6

Number of cases where death was a reported outcome: 1

■ More information on the search results



Verifiable death –Female –age 58

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 709421 | 12/02/2022 | 58 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Not suspected | Nausea Vomiting |

we know this was the case that had a death reported as the other reaction also associated with this case had a death reported also

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Reproductive system and breast disorders | Penile swelling | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 709938 | 14/02/2022 | 51 | М | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | ParaesthesiaPenile swellingPeripheral swelling |

■ 5 medicines selected between 17/02/2022 - 17/02/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

Infections and

infestations

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

dictionary.

Pneumonia aspiration

■ More information on the search results

| Medicine summary List of reports | | | | | | | | | | |
|---|---|------|---------------------------------|-----------------------------------|--|--|--|--|--|--|
| Medicine summary | | | | | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | | | | |
| Further information al | bout the medicine sumn | nary | | | | | | | | |
| Information on printin | ig search results | | | | | | | | | |
| Sort by: | | | | version of this | | | | | | |
| Number of cases - highest first | | | | | | | | | | |
| MedDRA system organ class | MedDRA reaction ter Click on a term below to se the MedlinePlus medical | | f Number of cases with a single | Number of cases where death was a | | | | | | |

suspected

medicine

reported

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 711210 | 17/02/2022 | 77 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Atrial fibrillation Haemorrhagic stroke Hypernatraemia Pneumonia aspiration |

■ 5 medicines selected between 18/02/2022 - 18/02/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Arrhythmia | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 711575 | 18/02/2022 | 55 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Arrhythmia Arteriosclerosis coronary artery Cardiac arrest Coronary artery thrombosis Dizziness Fatigue Hyperhidrosis |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary Medicine summary

List of reports

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Myocardial ischaemia | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 712335 | 21/02/2022 | 58 | М | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Not suspected | Cold sweat Hypertensive heart disease Myocardial ischaemia Vomiting |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|-----------------------------|---|-----------------|--|--|
| Infections and infestations | Sepsis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 712410 | 21/02/2022 | 93 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Abdominal pain Concomitant disease aggravated Dysuria Fluid retention Lower respiratory tract infection Pyrexia Renal failure Sepsis |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Nun

| adno A | ModDDA reaction torm | Number of |
|-------------------|----------------------|-----------|
| | | |
| mber of cases - h | ighest first | |

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac failure | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 713070 | 22/02/2022 | 66 | F | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Cardiac failure Concomitant disease aggravated |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 713567 | 23/02/2022 | 80 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Chest pain Concomitant disease progression |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 713647 | 24/02/2022 | 83 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Not suspected | Acute myocardial infarction Bradycardia Concomitant disease progression Dyspnoea Malaise Myocarditis Peripheral coldness Syncope Tachypnoea Troponin increased |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

<u>Medicine summary</u>

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|-----------------------------|---|-----------------|--|--|
| Infections and infestations | Pneumonia aspiration | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 713649 | 24/02/2022 | 82 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Anticoagulation drug level below therapeutic Encephalomalacia Miller Fisher syndrome Pneumonia aspiration Subacute inflammatory demyelinating polyneuropathy |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------|--|-----------------|--|--|
| Psychiatric disorders | Completed suicide | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 713726 | 24/02/2022 | 44 | М | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected Tradename not specified (atorvastatin) - Not suspected Benztropine Mesylate (benzatropine mesilate) - Not suspected Citalopram (citalopram hydrobromide) - Not suspected Clopixol Depot (zuclopenthixol decanoate) - Not suspected COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Not suspected Metformin (metformin hydrochloride) - Not suspected | Completed suicide Malaise |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 8

Number of cases with a single suspected medicine: 8

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Cardiac disorders | Pericarditis | 8 | 8 | 1 |

Verifiable death –Male –age 56

| Case numb | Report er entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|--------------|-------------------------|--------------|--------|--|---|
| 71396 | 3 24/02/2022 | 56 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Malaise Pericarditis |

We know this was the case that had a death reported also as the other reaction they reported also had a death reported

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Neoplasms benign, malignant and unspecified (incl cysts | Colon cancer | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 714462 | 25/02/2022 | 97 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Colon cancer |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------------|---|-----------------|--|--|
| Respiratory, thoracic and mediastinal | Respiratory failure | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 714463 | 25/02/2022 | 85 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Chest pain Respiratory failure |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 714466 | 25/02/2022 | 94 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Cardiac arrest |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summar | List of reports | | | |
|------------------------------------|--|--------------------|--|--|
| Medicine summa | ary | | | |
| The medicine summa adverse events. | ry groups reported adverse eve | ents together. Pat | ients may have re | ported multiple |
| Further information a | bout the medicine summary | | | |
| Information on printing | ng search results | | | |
| Sort by: | | | Print ve | rsion of this |
| Number of cases - hi | ghest first | | <u> </u> | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
| | | | | |

Verifiable death -Male -age 49

TOPOIL Case Medicines reported as **MedDRA** reaction Report Age **Gender** number entry date (yrs) being taken terms Click on a term below to search the MedlinePlus medical dictionary. 714456 25/02/2022 49 . COMIRNATY COVID-М Adverse event 19 vaccine following (tozinameran) immunisation Suspected Chest pain Oropharyngeal pain · Troponin I

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 714449 | 25/02/2022 | 68 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Concomitant disease progression |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Infections and infestations | Septic shock | 1 | 1 | 1 |

Verifiable death –Male –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 714391 | 25/02/2022 | - | М | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Septic shock |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 13

Number of cases with a single <u>suspected</u> medicine: 13

Number of cases where death was a reported outcome: 4

More information on the search results

| Medicine summary | <u>List of reports</u> | | | | |
|----------------------------------|---|---------------------|--|--|--|
| Medicine summary | | | | | |
| adverse events. | groups reported adverse evo | ents together. Pati | ents may have re | ported multiple | |
| | ~ | | | | |
| Information on printing | search results | | | | |
| Sort by: | | | | rsion of this | |
| Number of cases - highest first | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the <u>MedlinePlus</u> medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | |
| Injury, poisoning and procedural | Adverse event following immunisation | 13 | 13 | 4 | |

- 1 Verifiable death -Male -age 64
- 2 Verifiable death -Male -age 56

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 714464 | 25/02/2022 | 64 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Adverse event following immunisation |
| 714469 | 25/02/2022 | 56 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Adverse event following immunisation |

we know these are 2 of the 12 cases that had a death reported also because we could filter under age (18-64) and sex with BETA database

Verifiable death 65 or under - Female (unable to determine exact case)

| Reports (3 Medicine sui | sin mary - (1 rc | gle <u>suspected</u> med 3 DWS) Hover over | | oorted <u>deaths</u> 1 orting data and other optio | ns. Click on the dots to s | see more options. 😝 🏽 🎖 | Adverse event following immunisation Contusion Product administered to patient of inappr. Vaccination error |
|---------------------------------|----------------------|--|-------------------------|---|--|--|--|
| MedDRA syste | em organ class | MedDRA reacti | on term | Number of cases | Cases with a single suspected medicine | Cases where death was a reported outcome | Age (years) Select all 18 to 64 |
| Injury, poisoning complications | and procedural | Adverse event follo | wing immunisation | 3 | 3 | 1 | |
| List of repor | ts - (3 rows) | ? Hover ove | r the table to view exp | orting data and other opti | ons. Click on the dots to | see more options. → | Gender Select all Female Male |
| Case number | Report entry da | Age (years) | | dicines reported a | | ORA reaction terms | |
| 714451 | 25/02/2022 | 19 | | OMIRNATY COVID-19 va inameran) - Suspected | ccine • Adver | rse event following isation | |
| 714414 | 25/02/2022 | 31 | | DMIRNATY COVID-19 va inameran) - Suspected | ccine • Adver | rse event following isation | |
| 714366 | 25/02/2022 | 41 | | OMIRNATY COVID-19 va | ccine • Adve | se event following | |

One of these three cases had a death reported also but unable to establish which of the three the death is associated with

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

<u>List of reports</u>

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac failure | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 715290 | 28/02/2022 | 66 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Cardiac failure |

■ <u>5 medicines selected</u> between 28/02/2022 - 28/02/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 2 | 2 | 1 |

Verifiable death –Female –age 71

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 715291 | 28/02/2022 | 71 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Concomitant disease progression |

we know this is the case that had a death reported also as the other case had a reaction that did not have a death reported

■ 1 medicine selected between 28/02/2022 - 28/02/2022.

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 15

Number of cases with a single suspected medicine: 15

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first



| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 15 | 15 | 1 |

Verifiable death –Female –age 28

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 715082 | 28/02/2022 | 28 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

we know this is the case that had a death reported also when we use filters (age,sex etc) using the BETA database

■ 1 medicine selected between 02/03/2022 - 02/03/2022.

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

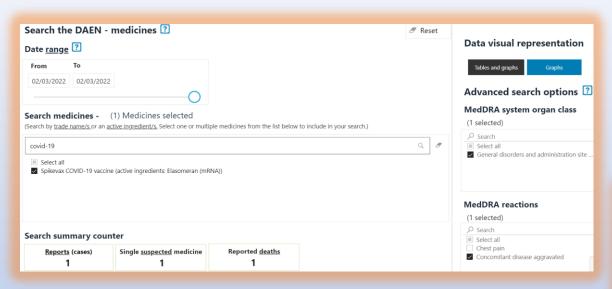
■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report Number of cases - highest first $\overline{}$ MedDRA MedDRA reaction term **Number of Number of Number of** cases where system organ cases with a Click on a term below to search cases class the MedlinePlus medical death was a single dictionary. suspected reported medicine outcome Cardiac disorders Acute myocardial infarction

Verifiable death –Male –age 70

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 716069 | 02/03/2022 | 70 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Acute myocardial infarction |

Verifiable death –Female –age 74



We know this is the case that had a death reported also as we can filter for age on BETA DAEN

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 716092 | 02/03/2022 | 74 | F | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Concomitant disease aggravated |



■ <u>5 medicines selected</u> between 04/03/2022 - 04/03/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------|--|-----------------|--|--|
| Investigations | Serum ferritin increased | 1 | 1 | 1 |

Verifiable death –Male –age 83

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 717139 | 04/03/2022 | 83 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Haemophagocytic lymphohistiocytosis Leukaemia Liver injury Sepsis Serum ferritin increased |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 1

More information on the search results

| Medicine summa | List of reports | | | | | | | |
|---|-----------------------|---|--------|---------------|--|--|--|--|
| Medicine summary | | | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | | |
| Further information about the medicine summary | | | | | | | | |
| Information on print | ing search results | | | | | | | |
| Sort by: | | | | rsion of this | | | | |
| Number of cases - h | nighest first | | report | | | | | |
| MedDRA MedDRA reaction term Number of cases Number of cases with a single death was a suspected medicine Number of cases where death was a suspected medicine | | | | | | | | |
| Cardiac disorders | Myocardial infarction | 3 | 3 | 1 | | | | |

Verifiable death –Male –age 72

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 717450 | 04/03/2022 | 99 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation Myocardial infarction |

| Medicine sur | | | | | | | |
|-------------------|----------------------|------------------------------|---------------------|--|------------------------------|---|---------------------|
| MedDRA syste | em organ class | MedDRA reacti | on term | Number of cases | Cases with a single suspecte | Cases where death | Age (years) |
| | | | | ▼ | medicine | outcome | Select all 18 to 64 |
| Cardiac disorders | <u>1</u> | <u>Myocardial infarction</u> | <u>on</u> | 1 | 1 | 1 | 65 and above |
| | | | | | | | |
| | | | | | | | Gender |
| List of report | ts - (1 rows) | ? Hover ove | r the table to viev | v exporting data and other opti | ons. Click on the dots to | see more options. → | Select all Male |
| Case number ▼ | Report entry date | Age (years) | Gender | Medicines reported a taken | s being MedI | ORA reaction terms | |
| 717450 | 4/03/2022 | 99 | Male | COMIRNATY COVID-19 va (tozinameran) - Suspected | immur | rse event following nisation cardial infarction | |

we know this case had a death reported also because we could filter for age (65+) with BETA DAEN

■ 1 medicine selected between 04/03/2022 - 04/03/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|--------------------------|
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |

■ 1 MedDRA Reaction Term selected.

Search results

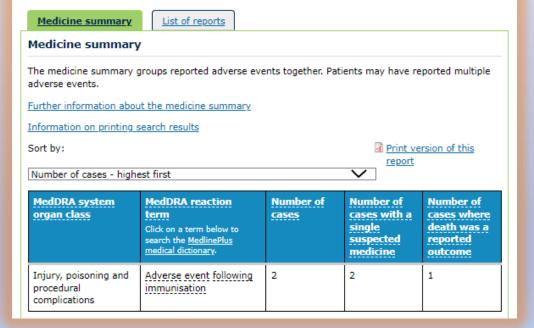
The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results



Verifiable death –Male –age 72

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 717392 | 04/03/2022 | - | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

| MedDRA system organ cla | ss MedDRA reacti | on term | Number of cases | Cases with a single suspected medicine | Cases where death was a reported outcome | Age (years) Select all 65 and above |
|--|---------------------|-------------------|--|--|--|--------------------------------------|
| Injury, poisoning and procedural complications | Adverse event follo | wing immunisation | 1 | 1 | 1 | ✓ Unknown |
| | | | | | | |
| | | | | | | Gender |
| List of reports - (1 rov | , Hover ove | | orting data and other optic | | | Select all Male |
| Case number Report entr | y date Age (years) | Gender Me tak | edicines reported as cen | being MedDR | A reaction terms | |
| 717392 4/03/202 | - | | OVID-19 Vaccine AstraZe AdOx1-S (Viral vector)) - | | event following ation | |

we know this case had a death reported also because we could filter for age (unknown) with BETA DAEN

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

class

Nervous system

disorders

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

the MedlinePlus medical

Cerebrovascular accident

dictionary.

■ More information on the search results

| Medicine summa | <u>ary</u> | <u>List of reports</u> | | | | | | | |
|---|------------|------------------------|-------------|-----------------|------------------------|-----------------------|--|--|--|
| Medicine summary | | | | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | | | |
| Further information | about th | ne medicine sumn | <u>nary</u> | | | | | | |
| Information on print | ting sear | rch results | | | | | | | |
| Sort by: Print version of this report | | | | | | | | | |
| Number of cases - highest first | | | | | | | | | |
| MedDRA system organ | | RA reaction tern | | Number of cases | Number of cases with a | Number of cases where | | | |

death was a

reported

outcome

suspected

medicine

Verifiable death –Male –age 78

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 717816 | 06/03/2022 | 78 | M | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected Norvasc (amlodipine) - Not suspected | Cerebrovascular accident Subdural haematoma |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 2 | 2 | 2 |

1 - Verifiable death -Male -age 46

1 - Verifiable death -Female -age 24

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 717851 | 07/03/2022 | 46 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected Candesartan (candesartan cilexetil) Not suspected | Cardiac arrest Chest pain Multiple organ dysfunction syndrome Neck pain Pain in jaw Pneumonia aspiration |
| 718277 | 07/03/2022 | 24 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Arrhythmia Cardiac arrest |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|--|-----------------|--|--|
| Gastrointestinal disorders | Mouth haemorrhage | 1 | 1 | 1 |

Verifiable death –Female –age 82

| | | | _ | | <u></u> |
|-----------------------|----------------------|--------------|--------|---|--|
| <u>Case</u> number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
| 717886 | 07/03/2022 | 82 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation Cardiac disorder Concomitant disease aggravated Contusion Decreased appetite Dry mouth Dysgeusia Epistaxis Mouth haemorrhage Neoplasm malignant Pain Restless legs syndrome Syncope |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

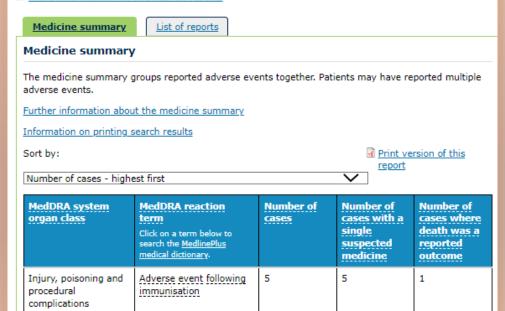
The results are shown in two tabs.

Number of reports (cases): 5

Number of cases with a single suspected medicine: 5

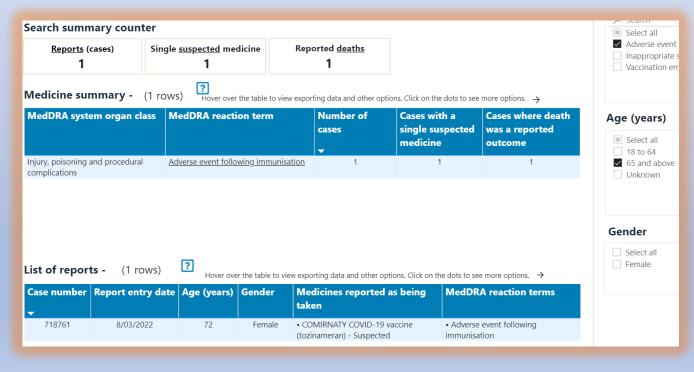
Number of cases where death was a reported outcome: 1

■ More information on the search results



Verifiable death –Male –age 72

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 718761 | 08/03/2022 | 72 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |



(we know this case had a death reported also because we could filter for age (65+) with BETA DAEN)

■ <u>5 medicines selected</u> between 09/03/2022 - 09/03/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

Verifiable death –Male –age 65

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 718925 | 09/03/2022 | 65 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Arthralgia Cardiac arrest Chest pain Dizziness Fatigue Hyperhidrosis Myocarditis |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

Verifiable death –Female –age 61

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 719134 | 09/03/2022 | 61 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

Verifiable death –Male –age 7

Medicines reported as Case **Gender MedDRA** reaction Report Age number entry date (yrs) being taken terms Click on a term below to search the MedlinePlus medical dictionary. 719838 11/03/2022 . COMIRNATY COVID-19 М Cardiac arrest vaccine (tozinameran) · Generalised tonic-- Suspected clonic seizure

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac failure | 1 | 1 | 1 |

Verifiable death –Female –age 71

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 720115 | 14/03/2022 | 71 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Not suspected | Cardiac failure Vaccine breakthrough infection |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Seizure | 1 | 1 | 1 |

Verifiable death –Female –age 89

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 720904 | 16/03/2022 | 89 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Dizziness Myalgia Myelodysplastic syndrome Nausea Pancytopenia Seizure Thrombocytopenia Weight decreased |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Haemorrhage intracranial | 1 | 1 | 1 |

Verifiable death -Male -age 64

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 720798 | 16/03/2022 | 64 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease aggravated Dry skin Fatigue Flushing Haemorrhage intracranial Headache Hypertension Malaise Rash Skin discolouration Tinnitus Vomiting |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



Verifiable death -Male -age 61

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 721150 | 17/03/2022 | 61 | M | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected Tradename not specified (celecoxib) - Not suspected Tradename not specified (oxycodone) - Not suspected COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Not suspected Viral vector) - Not suspected Nurofen (ibuprofen) - Not suspected | Cardiac arrest Cold sweat Dyspnoea Pallor Pulmonary embolism |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|---|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease progression | 1 | 1 | 1 |

Verifiable death -Male -age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 721416 | 17/03/2022 | - | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Concomitant disease progression COVID-19 |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results

| edicine summary |
|-----------------|
|-----------------|

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Cardiac disorders | Myocardial infarction | 2 | 2 | 1 |

Unable to determine which case Had a death reported also

Gender Medicines reported as MedDRA reaction Case Report Age (yrs) being taken number entry date terms Click on a term below to search the MedlinePlus medical dictionary. 17/03/2022 COMIRNATY COVID-19 721153 53 М Myocardial vaccine (tozinameran) infarction - Suspected 721408 17/03/2022 52 . COMIRNATY COVID-19 М Myocardial vaccine (tozinameran) infarction - Suspected

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

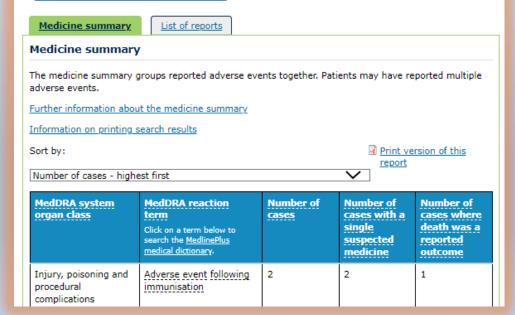
The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results



Verifiable death –Female –age 47

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 721483 | 17/03/2022 | 47 | F | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Adverse event following immunisation |

| Search summary | / counter | | | | | | Select all |
|--|--------------------|--|---------------------|--|--|--|--|
| Reports (case: | s) Sin | ngle <u>suspected</u> medi 1 | cine Re | ported <u>deaths</u> 1 | | | ✓ Adverse event following immunisation |
| Medicine summ | ary - (1 re | OWS) Pover over the | e table to view exp | orting data and other opti | ons. Click on the dots to see | e more options. \rightarrow | ☐ Incorrect dose administered |
| MedDRA system o | organ class | MedDRA reaction | n term | Number of cases | Cases with a single suspected medicine | Cases where death was a reported outcome | Age (years) |
| Injury, poisoning and p complications | rocedural | Adverse event following | ng immunisation | 1 | 1 | 1 | □ 18 to 64 |
| | | _ | | | | | Gender |
| List of reports - | (1 rows) | ? Hover over t | he table to view ex | porting data and other op | tions. Click on the dots to se | ee more options. → | Female Male |
| Case number Rep | oort entry d | ate Age (years) | | edicines reported : ken | as being MedDF | RA reaction terms | |
| 721483 | 17/03/2022 | 47 | | pikevax COVID-19 vacc asomeran (mRNA)) - Su | | e event following ation | |

We know this case had a death reported too as we can filter by age / sex with BETA DAEN

Selected medicines

| Trade name | Active ingredients |
|---------------------------|--------------------|
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 2 | 2 | 1 |

Verifiable death –Female –age 48

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 722440 | 21/03/2022 | 48 | F | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Adverse event following immunisation |

Adverse Event Following Immunisation (we know this case had a death reported also because we could filter for sex (female) with BETA DAEN)

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|---|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 3 | 3 | 1 |

Unable to confirm which one of these two cases had a death reported also

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 722357 | 21/03/2022 | 29 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |
| 722441 | 21/03/2022 | 55 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

Unable to confirm which of the two cases had a death reported also. We can confirm the two possibilities are 722357/29 Male or 722441/55 Male. We know it is one of these two by filtering for age on BETA DAEN

■ <u>5 medicines selected</u> between 22/03/2022 - 22/03/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------------|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal | Respiratory failure | 1 | 1 | 1 |

Verifiable death –Female –age 51

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 722927 | 22/03/2022 | 51 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Respiratory failure Thrombosis |

Verifiable death –Female –age 98

| Search sumn | nary counter | r | | | | | | Select all |
|-----------------------------------|---------------------|--------------------------------|------------------------|--|--|----------------------------------|----|--|
| Reports (| | Single <u>suspected</u> med 1 | icine Rep | orted <u>deaths</u> 1 | | | | ✓ Adverse event following immunisation ☐ Inappropriate schedule of product admini. ☐ Vaccination error ☐ Wrong product administered |
| Medicine sur | ` ` | rows) Hover over t | | Number of cases | Cases with a single suspected medicine | Cases where d | | Age (years) Select all 18 to 64 |
| Injury, poisoning a complications | and procedural | Adverse event follow | ving immunisation | 1 | 1 | 1 | | ✓ 65 and above Unknown |
| | | | | | | | | Gender |
| List of report | ts - (1 rows | s) Pover over | the table to view expo | orting data and other op | tions. Click on the dots t | o see more options. → | | ☐ Select all ☐ Female |
| Case number | Report entry | date Age (years) | Gender Me | dicines reported en | as being Med | DRA reaction term | ıs | |
| 722882 | 22/03/2022 | 98 | | MIRNATY COVID-19 v nameran) - Suspected | | erse event following nisation | | |

we know this is the case that had a death reported also as we can filter for age (65+) using BETA DAEN

■ <u>5 medicines selected</u> between 25/03/2022 - 25/03/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary Medicine summary

<u>List of reports</u>

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Number of cases - highest first

Print version of this report

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

Verifiable death –Female –age 9

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 724023 | 25/03/2022 | 9 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Cardiac arrest |

Verifiable death -Male -age 76

| Database of Adverse Event Notifications (DAEN) - medicines | | | | | | |
|--|-------------------------------------|--|--|--|---|--|
| Inclusion in DAEN - medicines do | es not mean that the adverse event | has been confirmed or that it was c | aused by a medicine or va | ccine. | | |
| Search summary count Reports (cases) 1 Medicine summary - | Single <u>suspected</u> medicine 1 | Reported <u>deaths</u> 1 to view exporting data and other optic | ons Click on the dats to see | mare ontions | (1 selected) Search Atrial fibrillation Atrial flutter Bradycardia Cardiac arrest Coronary artery disease Left ventricular hypertrophy | |
| MedDRA system organ class | | | Cases with a single suspected medicine | Cases where death was a reported outcome | Age (years) Select all 65 and above | |

| List of reports - (1 rows) Hover over the table to view exporting data and other options. Click on the dots to see more options. | | | | | | |
|---|-------------------|-------------|--------|---|--|--|
| Case number ▼ | Report entry date | Age (years) | Gender | Medicines reported as being taken | MedDRA reaction terms | |
| 724623 | 28/03/2022 | 76 | Male | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Not suspected | Cardiac arrest Haemoptysis Malaise Myocarditis Pneumonia Productive cough Rhinovirus infection Troponin increased | |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

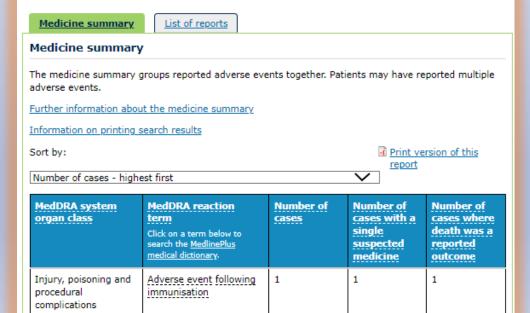
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results



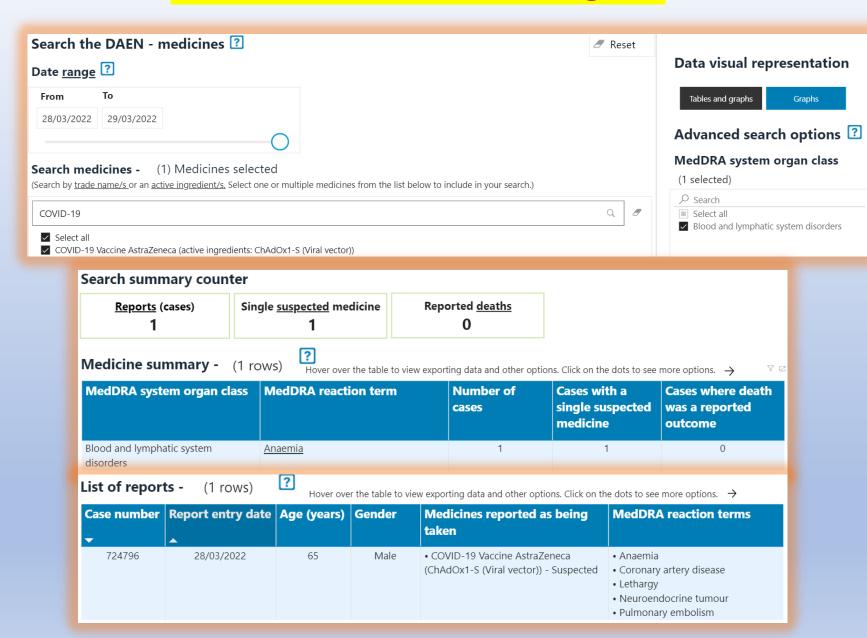
Verifiable Death – Male - age 6

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 724925 | 28/03/2022 | 6 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

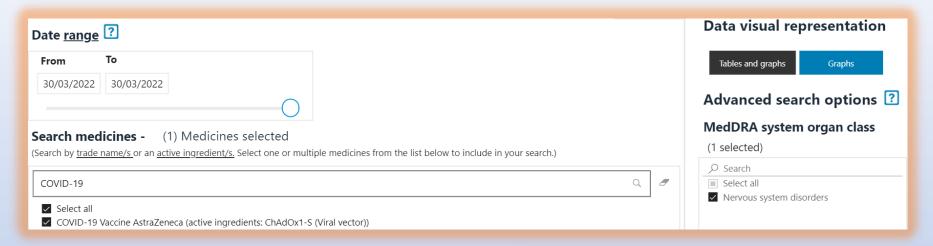
There was only one case of AEFI on this day and it had a death reported also. Therefore this 6 year old boy was the death reported. This is a screenshot from the TGA database proving it was reported

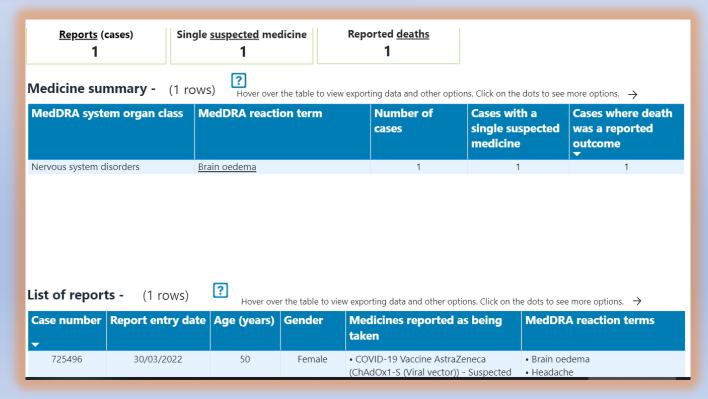
*This case has since been removed by the TGA. Why?

Verifiable Death – Male - age 65

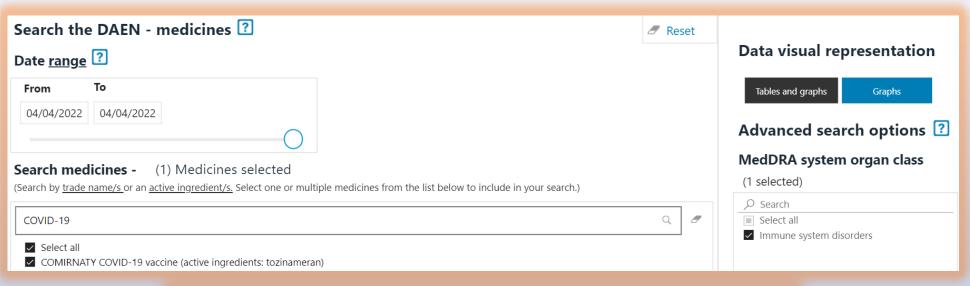


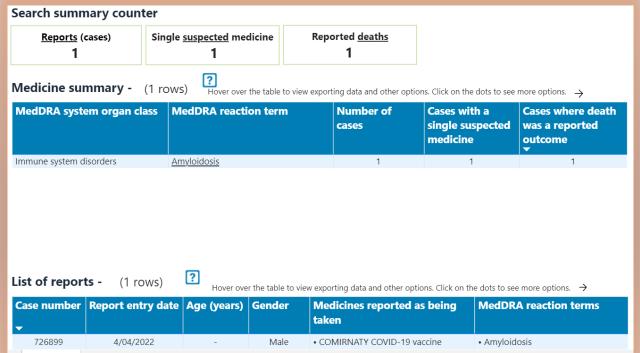
Verifiable Death – Female - age 50



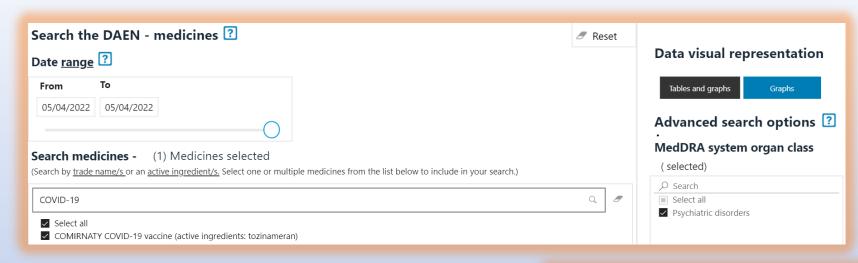


Verifiable Death – Male - age undisclosed

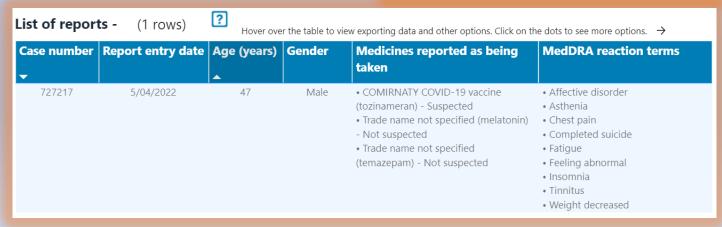




Verifiable Death – Male - age 47







■ 1 medicine selected between 06/04/2022 - 06/04/2022.

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 6

Number of cases with a single suspected medicine: 6

Number of cases where death was a reported outcome: 2

■ More information on the search results

| Medicine summary | | | | | | | | |
|---|--|---------------------|--|--|--|--|--|--|
| The medicine summary of adverse events. | groups reported adverse ev | ents together. Pati | ients may have re | ported multiple | | | | |
| Further information abou | ut the medicine summary | | | | | | | |
| Information on printing s | search results | | | | | | | |
| Sort by: Number of cases - high | est first | | Print ve | ersion of this | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | |
| Injury, poisoning and procedural | Adverse event following immunisation | 6 | 6 | 2 | | | | |

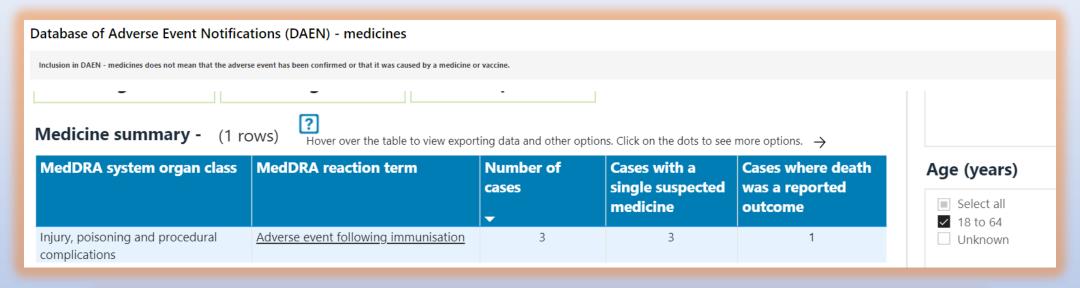
(we know this is one of the two deaths as we can filter for age 65+with BETA DAEN)

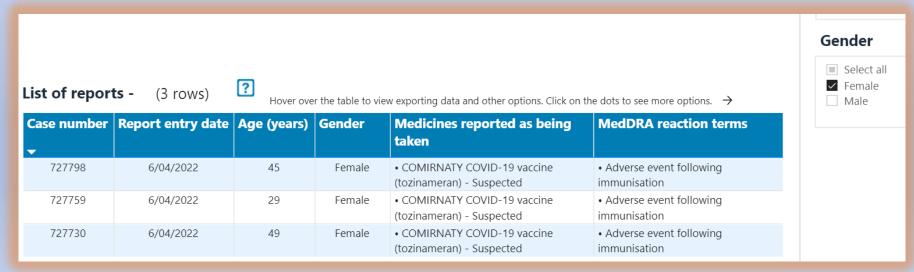
Verifiable Death – Male - age 73

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 727790 | 06/04/2022 | 73 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |



One of these three ladies had a death reported also (45/f, 29/f, 49/f)





■ <u>5 medicines selected</u> between 07/04/2022 - 07/04/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

Verifiable Death – Female - age 59

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 727971 | 07/04/2022 | 59 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Atrial fibrillation Atrioventricular block complete Cardiac arrest Chest pain Electrocardiogram ST segment depression Myocarditis Pericarditis Troponin increased |

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

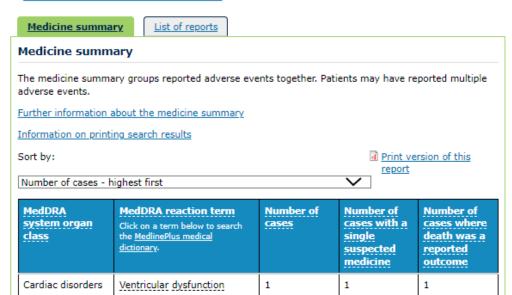
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



Verifiable Death – Female – age 21

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 729139 | 12/04/2022 | 21 | F | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected COMIRNATY COVID- 19 vaccine (tozinameran) - Not suspected | Abdominal pain Cardiac arrest Cardiogenic shock Echocardiogram abnormal Fatigue Femoral artery embolism Malaise Myocardial infarction Myocarditis Nausea Paraesthesia Peripheral ischaemia Pyrexia Renal impairment Spinal cord infarction Troponin increased Ventricular dysfunction |

■ 5 medicines selected between 13/04/2022 - 13/04/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 3

Number of cases where death was a reported outcome: 3

More information on the search results

Medicine summary List

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Number of cases - highest first

Print version of this report

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| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 3 | 3 | 3 |

- 1 Verifiable Death Male age 20
- 2 Verifiable Death Male age 63
- 1 Verifiable Death Male age 52

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 729612 | 13/04/2022 | 20 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |
| 729613 | 13/04/2022 | 63 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |
| 729614 | 13/04/2022 | 52 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

■ 5 medicines selected between 13/04/2022 - 13/04/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Medicine summary

MedDRA

class

system organ

Cardiac disorders

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

List of reports

MedDRA reaction term

the MedlinePlus medical

Myocardial ischaemia

dictionary.

Click on a term below to search

■ More information on the search results

| Medicine summary | |
|--|--|
| The medicine summary groups reported adverse events togeti adverse events. | her. Patients may have reported multiple |
| Further information about the medicine summary | |
| Information on printing search results | |
| Sort by: | Print version of this report |
| Number of cases - highest first | ~ |

Number of

cases

Number of

suspected

medicine

single

cases with a

Number of

cases where

death was a

reported

outcome

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 729619 | 13/04/2022 | 87 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Myocardial ischaemia |

■ 5 medicines selected between 13/04/2022 - 13/04/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

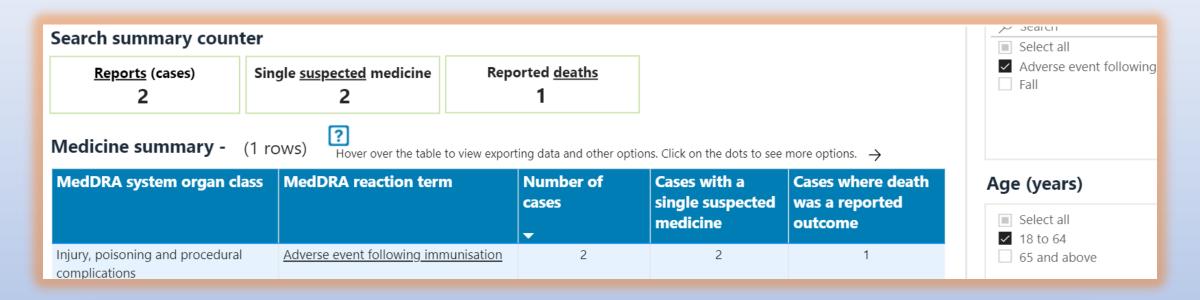
Print version of this report

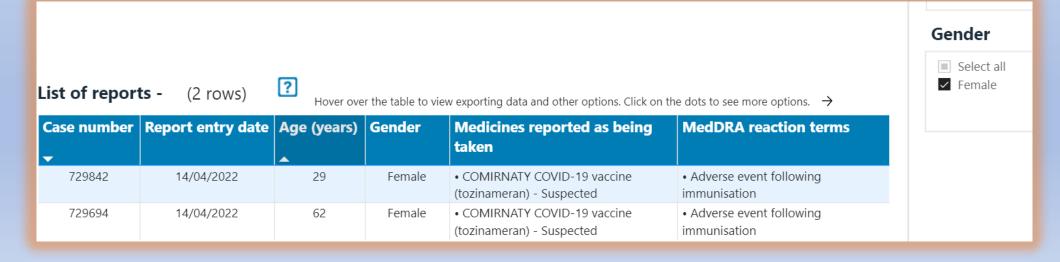
Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Atrial fibrillation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 729616 | 13/04/2022 | 91 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Atrial fibrillation |

One of these two ladies had a death reported also (29/F, 62/F)





Verifiable Death – Male - age 50

■ 1 medicine selected between 20/04/2022 - 20/04/2022.

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

■ 1 MedDRA Reaction Term selected.

Search results

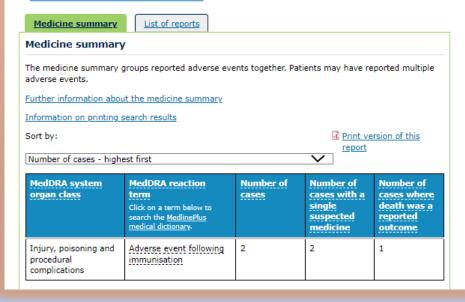
The results are shown in two tabs.

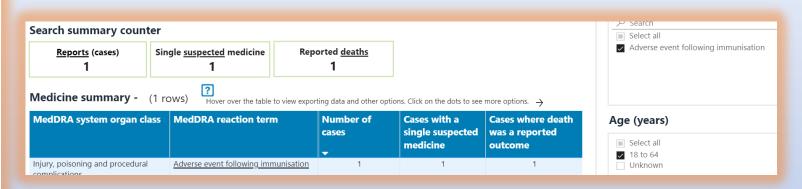
Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results





| List of repor | ts - (1 rows) | ? Hover ove | er the table to vie | w exporting data and other options. Click on t | the dots to see more options. \rightarrow |
|----------------|----------------------|-------------|---------------------|---|---|
| Case number ▼ | Report entry date | Age (years) | Gender | Medicines reported as being taken | MedDRA reaction terms |
| 730673 | 20/04/2022 | 50 | Male | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |
| | | | | | |

(we know a death was reported with this case as we can filter for age (18-64) with BETA DAEN)

■ 5 medicines selected between 22/04/2022 - 22/04/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 731225 | 22/04/2022 | 49 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Cardiac arrest |

■ 5 medicines selected between 22/04/2022 - 22/04/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 731219 | 22/04/2022 | 87 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cerebrovascular accident |

| Search summary count | >> Search ■ Select all | | | | |
|--|-------------------------------------|--------------------------------------|---|----------------------------------|---------------------|
| Reports (cases) | Single <u>suspected</u> medicine 1 | Reported <u>deaths</u> 1 | ☐ Arrhythmia☑ Myocardial infarction☐ Palpitations☐ Tachycardia | | |
| Medicine summary - | (1 " | to view exporting data and other opt | ions. Click on the dots to see | more options. \rightarrow | |
| MedDRA system organ class MedDRA reaction term | | n Number of cases | Cases with a single suspected | Cases where death was a reported | Age (years) |
| | | - | medicine | outcome | Select all 18 to 64 |
| Cardiac disorders <u>Myocardial infarction</u> | | 1 | 1 | 1 | ✓ 65 and above |
| | | | | | Unknown |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms |
|----------------|----------------------|--------------|--------|---|--|
| | | | | | Click on a term below to search the <u>MedlinePlus</u> medical dictionary. |
| 731223 | 22/04/2022 | 86 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Myocardial infarction |

■ 1 medicine selected between 22/04/2022 - 22/04/2022.

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

MedDRA system MedDRA reaction **Number of Number of** Number of organ class cases with a cases where term cases single death was a Click on a term below to suspected reported search the MedlinePlus medical dictionary. medicine outcome Injury, poisoning and Adverse event following procedural immunisation complications

- 1 Verifiable Death Male age 62
- 2 Verifiable Death Male age 20

Gender Medicines reported as **MedDRA** reaction Report Age Case number entry date (yrs) being taken terms Click on a term below to search the MedlinePlus medical dictionary. 22/04/2022 · Adverse event 731221 62 М COMIRNATY COVID-19 vaccine following (tozinameran) immunisation Suspected 731224 22/04/2022 20 М COMIRNATY COVID- Adverse event 19 vaccine following (tozinameran) immunisation Suspected

■ 1 medicine selected between 22/04/2022 - 22/04/2022.

Selected medicines

| Trade name | Active ingredients |
|---------------------------|--------------------|
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 731222 | 22/04/2022 | 69 | М | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 27/04/2022 - 27/04/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|------------------------------|---|-----------------|--|--|
| Infections and infestations | Pneumonia aspiration | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 731897 | 27/04/2022 | 84 | M | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Confusional state Dyspepsia Fall Hypotension Hypoxia Pneumonia aspiration Pyrexia Sepsis Vomiting |

■ <u>5 medicines selected</u> between 27/04/2022 - 27/04/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Pulmonary embolism | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 731715 | 27/04/2022 | 88 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Not suspected | Cardiac arrest Fall Pulmonary embolism |

■ 5 medicines selected between 27/04/2022 - 27/04/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Brain injury | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 731953 | 27/04/2022 | 42 | F | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Brain injury Encephalitis enteroviral |

| <u>Reports</u> (o 1 Medicine sur | | e <u>suspected</u> med 1 VS) Pover over | | eported <u>deaths</u> 1 porting data and other opt | ions. Click on the dots to see | e more options. | ☐ Acute myocardiai inta ☐ Atrial fibrillation ☐ Cardiac arrest ☐ Myopericarditis ☐ Palpitations |
|--|----------------------|---|---------------------|---|--|--|---|
| MedDRA syste | em organ class l | MedDRA reaction | on term | Number of cases | Cases with a single suspected medicine | Cases where death was a reported outcome | Age (years) Select all 65 and above |
| Cardiac disorders | <u> </u> | Atrial fibrillation | | 1 | 1 | 1 | Unknown |
| List of report | ts - (1 rows) | ? Hover over | the table to view e | xporting data and other op | otions. Click on the dots to se | ee more options. 🔿 | Gender ■ Select all ■ Female |
| Case number | Report entry date | e Age (years) | | Medicines reported aken | as being MedDF | RA reaction terms | |
| 731906 | 27/04/2022 | 69 | | COMIRNATY COVID-19 ozinameran) - Suspecte | | brillation ovascular accident | |

■ 1 medicine selected between 04/05/2022 - 04/05/2022.

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

Verifiable death –Female –age 91

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 733302 | 04/05/2022 | 91 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 04/05/2022 - 04/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

List of reports

More information on the search results

Medicine summary

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Renal and urinary disorders | Renal failure | 1 | 1 | 1 |

Verifiable death -Male -age 52

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 733335 | 04/05/2022 | 52 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Not suspected | Asthenia Blood creatine phosphokinase increased Hypoxia Lethargy Metabolic acidosis Myopathy Myositis Pneumonia Renal failure Rhabdomyolysis |

■ <u>5 medicines selected</u> between 06/05/2022 - 06/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single <u>suspected</u> medicine: 1

Number of cases where <u>death</u> was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

Verifiable death –Male –age 10

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 733723 | 06/05/2022 | 10 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 06/05/2022 - 06/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Acute myocardial infarction | 2 | 2 | 1 |

Verifiable death –Female –age 80

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 733760 | 06/05/2022 | 80 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Acute myocardial infarction |

■ <u>5 medicines selected</u> between 09/05/2022 - 09/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summa | <u>List of reports</u> | | | | | | | |
|--|--|-----------------|--|--|--|--|--|--|
| Medicine summary | | | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | | |
| Further information | about the medicine summary | | | | | | | |
| Information on print | ing search results | | | | | | | |
| Sort by: Print version of this report Print version of th | | | | | | | | |
| Number of cases - h | nighest first | | V | | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | | |
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 | | | | |

Verifiable death –Female –age 98

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 734081 | 09/05/2022 | 98 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Cardiac arrest |

■ <u>5 medicines selected</u> between 10/05/2022 - 10/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

Verifiable death –Male –age 5

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 734187 | 10/05/2022 | 5 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Abdominal pain Cardiac arrest |

■ 5 medicines selected between 10/05/2022 - 10/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple

Further information about the medicine summary

Information on printing search results

Sort by:

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Renal and urinary disorders | Renal failure | 1 | 1 | 1 |

Verifiable death –Female –age 80

Gender **Medicines reported MedDRA reaction terms** Case Report Age entry date (yrs) as being taken number Click on a term below to search the MedlinePlus medical dictionary. 734396 10/05/2022 80 COMIRNATY Haemophagocytic COVID-19 vaccine lymphohistiocytosis (tozinameran) - Hepatitis · Renal failure Suspected

■ 5 medicines selected between 10/05/2022 - 10/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

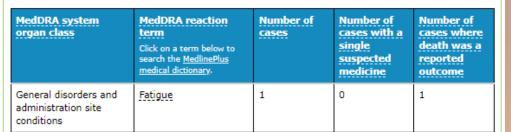
Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first



Verifiable death –Female –age 78

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 734205 | 10/05/2022 | 78 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected Influenza Vaccine (TNS) (Influenza virus haemagglutinin) - Suspected | Aortic dissection rupture Fatigue Nausea Pain Pyrexia |

■ 1 medicine selected between 10/05/2022 - 10/05/2022.

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

Verifiable death Male –age 33

| <u>Case</u> number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|-----------------------|----------------------|--------------|--------|---|---|
| 734407 | 10/05/2022 | 33 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 11/05/2022 - 11/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summary | List of reports | | | | | | |
|---|--|-----------------|--|--|--|--|--|
| Medicine summary | | | | | | | |
| The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. | | | | | | | |
| Further information ab | out the medicine summary | | | | | | |
| Information on printing | search results | | | | | | |
| Sort by: | | | | rsion of this | | | |
| Number of cases - hig | hest first | | report | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | |
| Investigations | Fibrin D dimer increased | 1 | 1 | 1 | | | |

Verifiable death Male –age 68

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 734522 | 11/05/2022 | 68 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Fibrin D dimer increased Pleural effusion Pulmonary embolism |

■ 5 medicines selected between 12/05/2022 - 12/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 1 | 1 | 1 |

Verifiable death Female –age 91

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 734859 | 12/05/2022 | 91 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Cerebrovascular accident |

■ 5 medicines selected between 12/05/2022 - 12/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

Verifiable death Male –age 78

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 734868 | 12/05/2022 | 78 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Acute myocardial infarction Bradycardia Cardiac arrest Chest pain |

■ 1 medicine selected between 12/05/2022 - 12/05/2022.

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Print version of this Sort by: $\overline{}$

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Myocardial infarction | 1 | 1 | 1 |

report

Verifiable death Male –age 76

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 734854 | 12/05/2022 | 76 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Myocardial infarction |

■ <u>5 medicines selected</u> between 16/05/2022 - 16/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------|--|-----------------|--|--|
| Investigations | Coma scale abnormal | 1 | 1 | 1 |

Verifiable death Female –age 64

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 735475 | 16/05/2022 | 64 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Coma scale abnormal Fall Hypoxia |

■ <u>5 medicines selected</u> between 18/05/2022 - 18/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

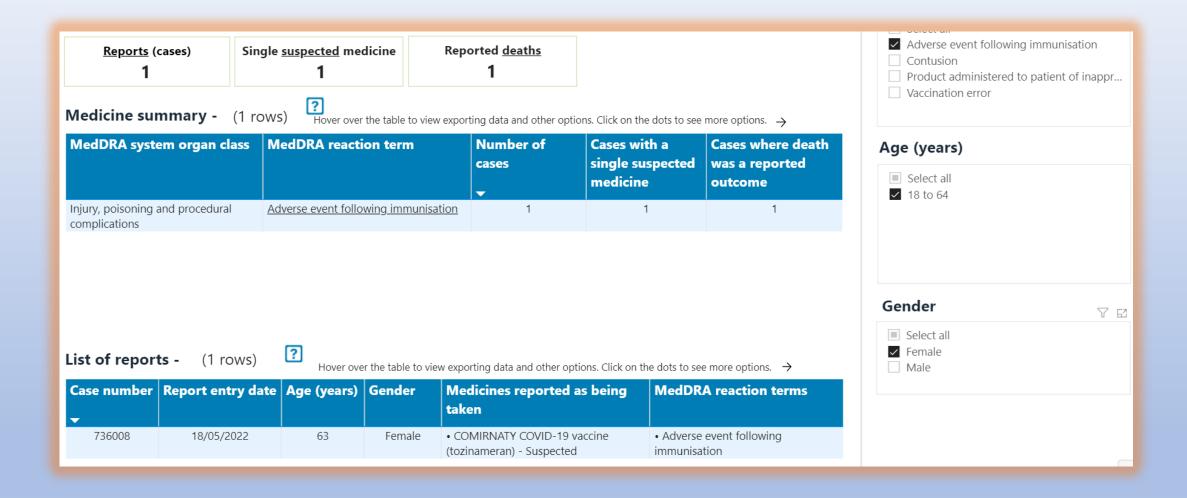
Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Myocardial infarction | 1 | 1 | 1 |

Verifiable death Female –age 77

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 736007 | 18/05/2022 | 77 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Myocardial infarction |

Verifiable death Male –age 68



■ 1 medicine selected between 18/05/2022 - 18/05/2022.

Selected medicines

| Trade name | Active ingredients |
|---------------------------|--------------------|
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

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Number of cases - highest first

Sort by:

Print version of this report

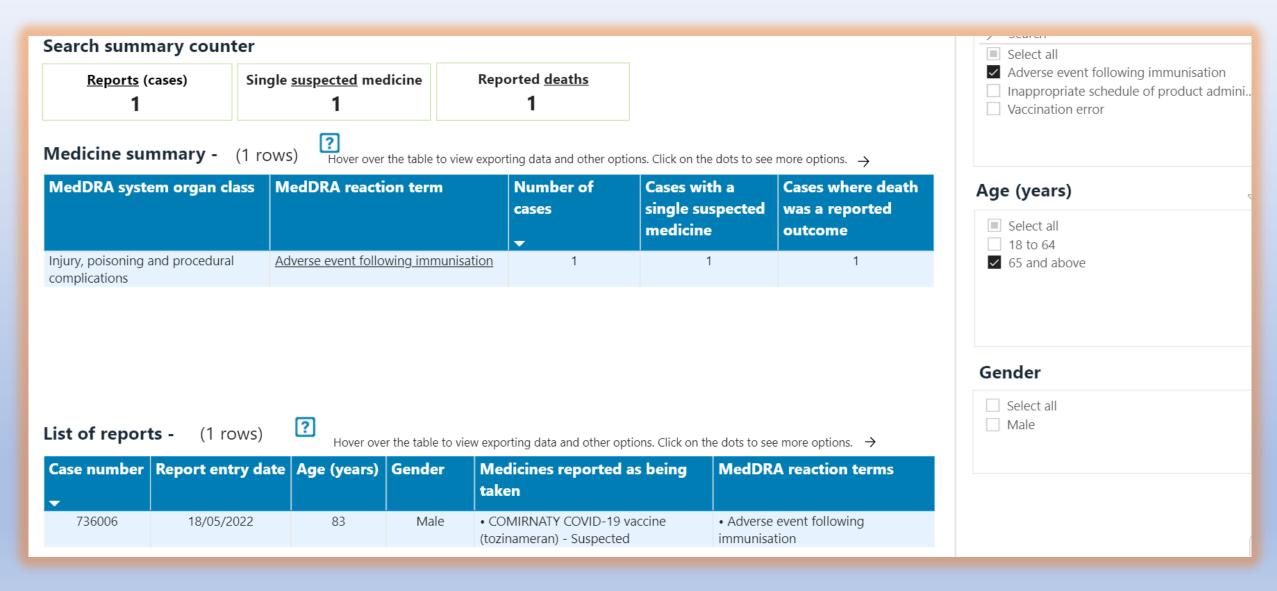
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| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

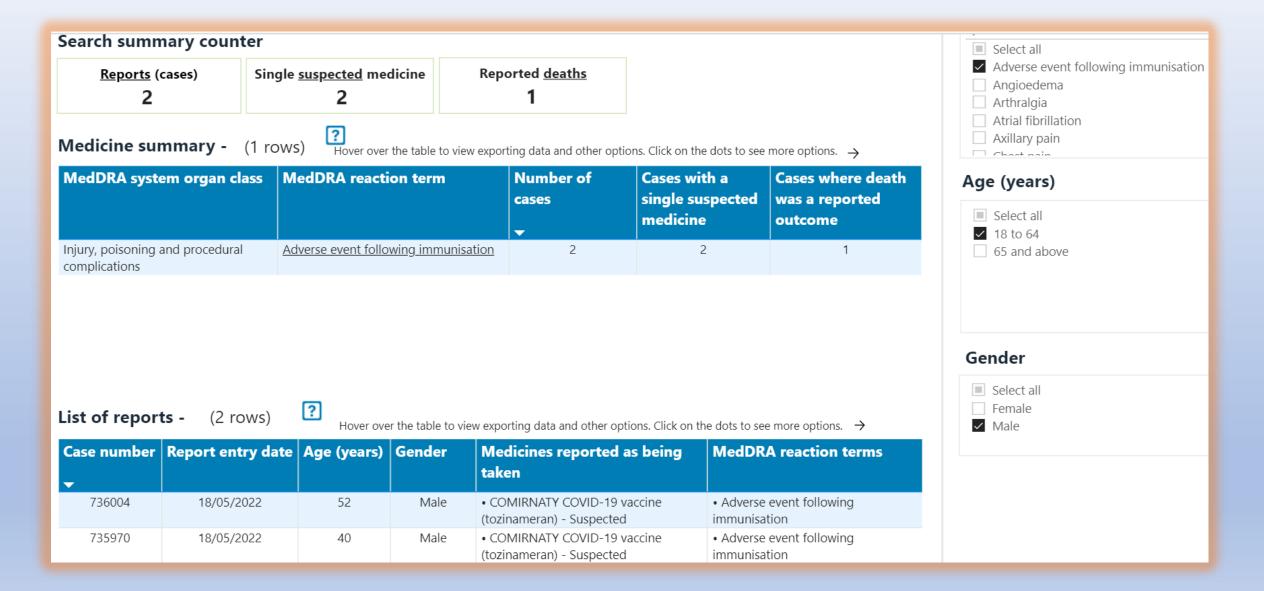
Verifiable death Female –age 75

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 736010 | 18/05/2022 | 75 | F | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Adverse event following immunisation |

Verifiable death Male –age 68



Unable to confirm which of these two Cases had a death reported also



■ 5 medicines selected between 19/05/2022 - 19/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Nervous system disorders | Depressed level of consciousness | 1 | 1 | 1 |

Verifiable death Male –age 88

Medicines reported as Case Report Age Gender MedDRA reaction number entry date (yrs) being taken terms Click on a term below to search the MedlinePlus medical dictionary. 736180 19/05/2022 88 Μ • Spikevax COVID-19 Adverse event vaccine (Elasomeran following (mRNA)) - Suspected immunisation · Depressed level of consciousness Tachypnoea

■ 5 medicines selected between 19/05/2022 - 19/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|----------------------------|--|-----------------|--|--|
| Gastrointestinal disorders | Intestinal ischaemia | 1 | 1 | 1 |

Verifiable death Female –age 86

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 736177 | 19/05/2022 | 86 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Intestinal ischaemiaMesenteric vein thrombosis |

■ <u>5 medicines selected</u> between 20/05/2022 - 20/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

Verifiable death Male –age 28

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 736431 | 20/05/2022 | 28 | М | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 20/05/2022 - 20/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Ventricular tachycardia | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 736234 | 20/05/2022 | 64 | M | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Asthenia Blood magnesium decreased Concomitant disease progression Decreased appetite Dyspnoea Fatigue Myalgia Pain in extremity Pulmonary oedema Ventricular tachycardia |

■ 5 medicines selected between 21/05/2022 - 21/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

Verifiable death Female –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 736519 | 21/05/2022 | - | F | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 21/05/2022 - 21/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of cases - highest first

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Sort by: Print version of this report

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Cardiac disorders | Tachycardia | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 736486 | 21/05/2022 | 40 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Abdominal pain Decreased appetite Haematuria Headache Malaise Multiple organ dysfunction syndrome Myalgia Ovarian cancer Pain in extremity Septic shock Tachycardia Vomiting |

■ 5 medicines selected between 23/05/2022 - 23/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

■ More information on the search results



1 - Verifiable death sex and age undisclosed2 - Verifiable death sex and age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 736855 | 23/05/2022 | - | - | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |
| 736856 | 23/05/2022 | - | - | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

■ 5 medicines selected between 25/05/2022 - 25/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

<u>Medicine summary</u>

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Cardiac disorders | Myocardial infarction | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 737282 | 25/05/2022 | 52 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Myocardial infarction |

■ 5 medicines selected between 25/05/2022 - 25/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

<u>Medicine summary</u>

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|--|-----------------|--|--|
| Respiratory, thoracic and mediastinal disorders | Respiratory failure | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 737150 | 25/05/2022 | 80 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Not suspected | Concomitant disease progression Fatigue Pulmonary embolism Respiratory failure |

■ 1 medicine selected between 25/05/2022 - 25/05/2022.

Selected medicines

| Trade name | Active ingredients |
|----------------------------|--------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single <u>suspected</u> medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

Verifiable death Male –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 737281 | 25/05/2022 | - | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

■ 1 medicine selected between 25/05/2022 - 25/05/2022.

Selected medicines

| Trade name | Active ingredients |
|----------------------------|-----------------------------|
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |

■ 1 MedDRA Reaction Term selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first



| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Concomitant disease aggravated | 1 | 1 | 1 |

Verifiable death Male –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 737280 | 25/05/2022 | - | М | NUVAXOVID COVID-19 Vaccine (SARS-CoV-2 rS (NVX-CoV2373)) - Suspected | Concomitant disease aggravated |

■ 5 medicines selected between 26/05/2022 - 26/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 737453 | 26/05/2022 | 75 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

■ 5 medicines selected between 26/05/2022 - 26/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Myocardial infarction | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 737455 | 26/05/2022 | 71 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Myocardial infarction |

■ <u>5 medicines selected</u> between 26/05/2022 - 26/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

<u>Medicine summary</u>

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac failure | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 737452 | 26/05/2022 | 89 | М | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Cardiac failure |

■ <u>5 medicines selected</u> between 30/05/2022 - 30/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Renal and urinary disorders | Renal failure | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 738131 | 30/05/2022 | 56 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Arteriosclerosis Renal failure |

■ <u>5 medicines selected</u> between 30/05/2022 - 30/05/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single $\underline{\text{suspected}}$ medicine: $\mathbf{1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Vascular disorders | Deep vein thrombosis | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 738130 | 30/05/2022 | 80 | F | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Deep vein thrombosis Pulmonary embolism |

■ 5 medicines selected between 02/06/2022 - 02/06/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

■ More information on the search results

<u>Medicine summary</u>

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Number of cases - highest first

Print version of this report

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 2 | 2 | 2 |

1- Verifiable death Male –age 552- Verifiable death Male –age 61

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 738686 | 02/06/2022 | 55 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |
| 738687 | 02/06/2022 | 61 | М | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 02/06/2022 - 02/06/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|--|-----------------|--|--|
| Renal and urinary disorders | Renal failure | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 738569 | 02/06/2022 | 53 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Acute pulmonary oedema Haemophagocytic lymphohistiocytosis Influenza A virus test positive Renal failure |

■ <u>5 medicines selected</u> between 03/06/2022 - 03/06/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

■ More information on the search results

Medicine summary List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Number of cases - highest first

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| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 2 | 2 | 2 |

1- Verifiable death Female –age 48

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 738905 | 03/06/2022 | 48 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |
| 738913 | 03/06/2022 | 86 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

■ 5 medicines selected between 07/06/2022 - 07/06/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Cerebrovascular accident | 1 | 0 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 739485 | 07/06/2022 | 78 | M | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected FLUAD QUAD (Influenza virus haemagglutinin) - Suspected Prevenar 13 (Pneumococcal purified capsular polysaccharides) - Suspected | Basilar artery thrombosis Cerebrovascular accident Pneumonia |

■ 5 medicines selected between 08/06/2022 - 08/06/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 739996 | 08/06/2022 | 38 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 10/06/2022 - 10/06/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

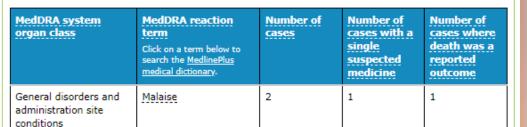
Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first



| Case | | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|------|----|----------------------|--------------|--------|---|--|
| 7402 | 71 | 10/06/2022 | 79 | М | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected Influenza Vaccine (TNS) (Influenza virus haemagglutinin) - Suspected | Chest discomfort Malaise |

■ <u>5 medicines selected</u> between 14/06/2022 - 14/06/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 2

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 2

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 2 | 2 | 2 |

1- Verifiable death Male –age 842- Verifiable death Female –age 74

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 740784 | 14/06/2022 | 84 | М | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Adverse event following immunisation |
| 740785 | 14/06/2022 | 74 | F | NUVAXOVID COVID-19 Vaccine (SARS-CoV-2 rS (NVX-CoV2373)) - Suspected | Adverse event following immunisation |

■ 5 medicines selected between 14/06/2022 - 14/06/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Nervous system disorders | Haemorrhagic stroke | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 740787 | 14/06/2022 | 54 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Haemorrhagic stroke Systolic hypertension |

■ <u>5 medicines selected</u> between 22/06/2022 - 22/06/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Respiratory, thoracic and mediastinal disorders

Number of cases with a single suspected medicine: 0

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summary | <u>List of reports</u> | | | |
|---|---|---------------------|-------------------------------|-----------------------------------|
| Medicine summary | , | | | |
| The medicine summary of adverse events. | groups reported adverse eve | ents together. Pati | ents may have re | ported multiple |
| Further information abou | ut the medicine summary | | | |
| Information on printing s | search results | | | |
| Sort by: | | | | rsion of this |
| Number of cases - high | est first | | report | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to | Number of cases | Number of cases with a single | Number of cases where death was a |

reported

outcome

suspected

medicine

Click on a term below to

search the MedlinePlus

Respiratory failure

medical dictionary.

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 741926 | 22/06/2022 | 73 | M | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected FLUAD QUAD (Influenza virus haemagglutinin) - Suspected COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Not suspected | Respiratory failure Respiratory tract infection |

■ <u>5 medicines selected</u> between 24/06/2022 - 24/06/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Medicine summary

MedDRA

class

system organ

Cardiac disorders

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

List of reports

MedDRA reaction term

the MedlinePlus medical

dictionary.

Myocarditis

Click on a term below to search

More information on the search results

Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Sort by: Print version of this report Number of cases - highest first

Number of

cases

Number of

suspected

medicine

single

cases with a

Number of

cases where

death was a

reported

outcome

Verifiable death Female –age 78

Gender Medicines reported as Report **MedDRA** reaction Case Age (yrs) being taken entry date number terms Click on a term below to search the MedlinePlus medical dictionary. 742259 24/06/2022 78 . COMIRNATY COVID-· Concomitant disease 19 vaccine aggravated (tozinameran) - Hyperhidrosis Suspected Myocarditis Pericarditis • Pleuritic pain Pneumonia

■ <u>5 medicines selected</u> between 27/06/2022 - 27/06/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single <u>suspected</u> medicine: **1**Number of cases where <u>death</u> was a reported outcome: **1**

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|---|-----------------|--|--|
| Injury, poisoning and procedural complications | Subdural haematoma | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 742514 | 27/06/2022 | 86 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Fall Subdural haematoma |

■ <u>5 medicines selected</u> between 27/06/2022 - 27/06/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|---|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 742513 | 27/06/2022 | 58 | М | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 01/07/2022 - 01/07/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|---|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 743229 | 01/07/2022 | 75 | М | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 04/07/2022 - 04/07/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: 2

Number of cases where death was a reported outcome: 3

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 3 | 2 | 3 |

- 1- Verifiable death Female –age 82
 - 2- Verifiable death Male –age 68
 - 3- Verifiable death Male –age 21

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 743439 | 04/07/2022 | 82 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected Influenza Vaccine (TNS) (Influenza virus haemagglutinin) - Suspected | Adverse event following immunisation |
| 743453 | 04/07/2022 | 68 | М | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |
| 743489 | 04/07/2022 | 21 | М | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

■ 5 medicines selected between 04/07/2022 - 04/07/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Traumatic haemorrhage | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 743450 | 04/07/2022 | 59 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Concomitant disease aggravated Fall Traumatic haemorrhage |

| Reports (o | nmary - (1 ro | gle <u>suspected</u> med 1 OWS) Hover over | | eported <u>deaths</u> 1 porting data and other optic | ns. Click on the dots to see | e more options. → | ☐ Balance disorder ☑ Encephalopathy ☐ Headache ☐ Lethargy |
|------------------|-----------------|---|-----------------------|---|-------------------------------|----------------------------------|---|
| MedDRA syste | em organ class | MedDRA reacti | | Number of cases | Cases with a single suspected | Cases where death was a reported | Age (years) |
| | | | | | medicine | outcome | ☐ Select all ☐ 65 and above |
| Nervous system d | isorders | <u>Encephalopathy</u> | | 1 | 1 | 1 | os and above |
| | | | | | | | Gender |
| List of report | ts - (1 rows) | ? Hover ove | r the table to view e | xporting data and other opti | ons. Click on the dots to se | e more options. 🗡 | Select all Female |
| Case number | Report entry da | Age (years) | | Medicines reported a aken | s being MedDR | A reaction terms | |
| 744119 | 9/07/2022 | 75 | ((• - | COVID-19 Vaccine AstraZo ChAdOx1-S (Viral vector)) Trade name not specified Not suspected Trade name not specified lot suspected | Suspected (amlodipine) | alopathy | |

■ <u>5 medicines selected</u> between 11/07/2022 - 11/07/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Number of cases - highest first

Print version of this report

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardio-respiratory arrest | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 744231 | 11/07/2022 | 96 | F | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected COVID-19 Vaccine AstraZeneca (ChAdOx1- S (Viral vector)) - Not suspected Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Not suspected | Cardio-respiratory arrest Nausea Pain |

■ 5 medicines selected between 11/07/2022 - 11/07/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

Immune system

disorders

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

Immunisation reaction

■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: <u>report</u> Number of cases - highest first $\overline{}$ MedDRA **Number of Number of MedDRA reaction term Number of** cases where system organ cases with a Click on a term below to search cases class the MedlinePlus medical single death was a dictionary. suspected reported

1

outcome

medicine

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 744306 | 11/07/2022 | 14 | F | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Immunisation reaction |

■ <u>5 medicines selected</u> between 11/07/2022 - 11/07/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

system organ

Cardiac disorders

class

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report ~ Number of cases - highest first MedDRA MedDRA reaction term **Number of Number of** Number of

cases

Click on a term below to search the MedlinePlus medical

dictionary.

Atrial fibrillation

cases where

death was a

reported

outcome

cases with a

single

suspected medicine

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 744250 | 11/07/2022 | 80 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Atrial fibrillation Cardiac failure congestive Concomitant disease aggravated Urinary retention |

■ <u>5 medicines selected</u> between 14/07/2022 - 14/07/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Malaise | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 744712 | 14/07/2022 | 71 | М | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | • COVID-19 • Fatigue • Malaise |

■ <u>5 medicines selected</u> between 18/07/2022 - 18/07/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: ${\bf 1}$

More information on the search results

$\underline{\text{Medicine summary}}$

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

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| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 745130 | 18/07/2022 | 30 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

■ 5 medicines selected between 21/07/2022 - 21/07/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

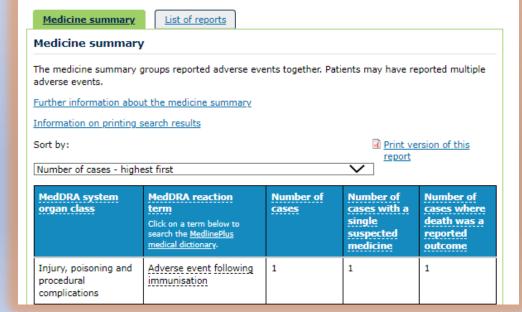
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



Verifiable death Male –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 745480 | 21/07/2022 | - | М | COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 21/07/2022 - 21/07/2022.

Selected medicines

| Trade name | Active ingredients | |
|------------------------------|---------------------------------------|--|
| COMIRNATY COVID-19 vaccine | tozinameran | |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) | |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) | |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) | |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) | |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${\bf 0}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the <u>MedlinePlus</u> medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---|---|-----------------|--|--|
| Neoplasms benign, malignant and unspecified (incl cysts | Malignant melanoma | 1 | 0 | 1 |

Verifiable death Male –age undisclosed

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 745472 | 21/07/2022 | - | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Headache Malignant melanoma Sensory loss |

■ <u>5 medicines selected</u> between 22/07/2022 - 22/07/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|---|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

Verifiable death Male –age 90

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 745704 | 22/07/2022 | 90 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

■ 5 medicines selected between 25/07/2022 - 25/07/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected

Search results

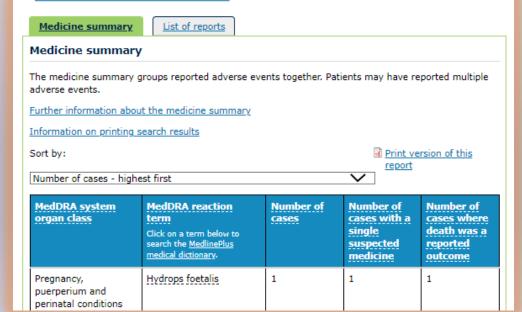
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results



Verifiable death Male –age <1 We know the baby died as report was for a male

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 746201 | 25/07/2022 | - | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Congestive cardiomyopathy Hydrops foetalis Pericardial effusion Skin oedema Tricuspid valve incompetence Ventricular dysfunction |

What causes hydrops fetalis?

The condition occurs when a disease or medical condition affects the body's ability to manage fluid. There are three main causes for this type, heart or lung problems, severe anemia (such as from thalassemia or infections), and genetic or developmental problems, including Turner syndrome. 24 May 2021

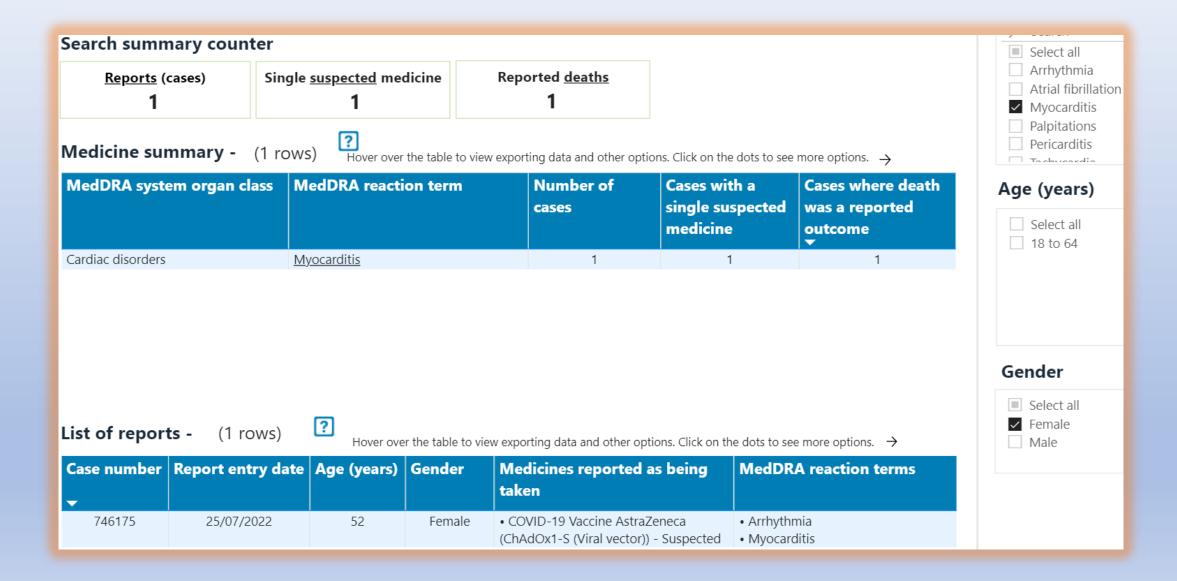
Can a baby survive hydrops fetalis?

The prognosis for babies with hydrops fetalis depends on the underlying cause of the condition. Overall, however, **the survival rate is low**. More than half of all babies with the condition die before birth or soon after delivery.

Verifiable death Male –age 77

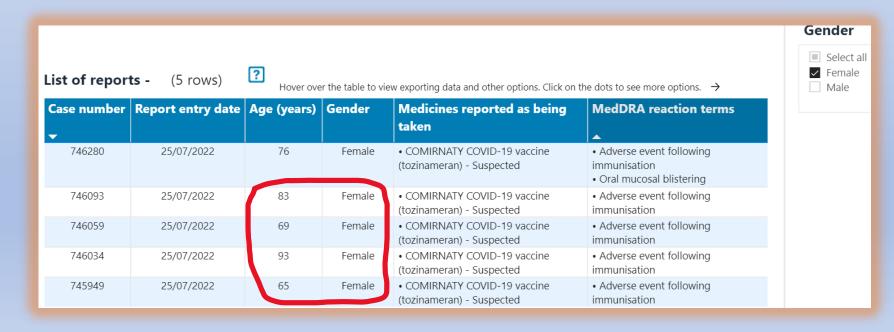
| Search sumn | nary counte | r | | | | | Arrhythmia |
|-------------------|----------------|---|----------------------|---|-------------------------------|----------------------------------|---|
| Reports (d | cases) | Single <u>suspected</u> med 1 | icine Re | eported <u>deaths</u> 1 | | | ☐ Atrial fibrillation☐ Cardiac failure✓ Cardio-respiratory arrest |
| Medicine sur | nmary - (1 | rows) Pover over t | he table to view exp | porting data and other optic | ons. Click on the dots to see | e more options. \rightarrow | ☐ Myocardial infarction☐ Myocarditis☐ Description |
| MedDRA syste | em organ class | MedDRA reaction | on term | Number of cases | Cases with a single suspected | Cases where death was a reported | Age (years) |
| | | | | Cases | medicine | outcome | Select all 65 and above |
| Cardiac disorders | | <u>Cardio-respiratory a</u> | rrest | 1 | 1 | 1 | os ana above |
| | | | | | | | |
| | | | | | | | Gender |
| List of report | | , Hover over | | porting data and other opt | | | Select all Male |
| Case number ▼ | Report entry | date Age (years) | | ledicines reported a aken | as being MedDR | A reaction terms | |
| 746173 | 25/07/2022 | 2 77 | | COVID-19 Vaccine AstraZ hAdOx1-S (Viral vector)) | | | |

Verifiable death Female –age 52



Two of these four women also had a death reported

| | ccine (active ingredients: tozinameran e (active ingredients: Elasomeran (mR | | | | MedDRA reactions (1 selected) Search |
|---|---|---|--|--|--|
| Reports (cases) | Single <u>suspected</u> medicine | Reported <u>deaths</u> 2 To view exporting data and other opi | | | ■ Select all ✓ Adverse event following immunisation Extra dose administered Inappropriate schedule of product admin Limb injury Vaccination error |
| Medicine summary - MedDRA system organ cl | | | Cases with a single suspected medicine | Cases where death was a reported outcome | Age (years) Select all |
| Injury, poisoning and procedura complications | Adverse event following imm | nunisation 5 | 5 | 2 | ☐ 18 to 64 ✓ 65 and above ☐ Unknown |



■ 5 medicines selected between 27/07/2022 - 27/07/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 3

Number of cases with a single suspected medicine: ${\bf 3}$

Number of cases where death was a reported outcome: 3

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 3 | 3 | 3 |

1- Case No 746681 – 90 Female

2 - Case No 746683 - 78 Female

3 - Case No 746684 - 68 Male

| Case number | Report entry date | Age (yrs) | <u>Gender</u> | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|---------------|---|---|
| 746681 | 27/07/2022 | 90 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |
| 746683 | 27/07/2022 | 78 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |
| 746684 | 27/07/2022 | 68 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 29/07/2022 - 29/07/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 1 | 1 | 1 |

Case No 747006 – 53 Male

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 747006 | 29/07/2022 | 53 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |

■ <u>5 medicines selected</u> between 29/07/2022 - 29/07/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Injury, poisoning and procedural complications | Liver transplant failure | 1 | 1 | 1 |

Case No 746926 – 24 Female

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 746926 | 29/07/2022 | 24 | F | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | COVID-19 Liver transplant failure |

■ 5 medicines selected between 30/07/2022 - 30/07/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

and polyps)

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary List of reports Medicine summary The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events. Further information about the medicine summary Information on printing search results Print version of this Sort by: report Number of cases - highest first $\overline{}$ MedDRA system MedDRA reaction **Number of Number of Number of** organ class cases with a cases where term cases Click on a term below to search the MedlinePlus single death was a reported suspected medical dictionary. medicine outcome Neoplasms benign, Neoplasm malignant malignant and unspecified (incl cysts

Case No 747066 - 73 Male

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 747066 | 30/07/2022 | 73 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Fatigue Malaise Neoplasm malignant Weight decreased |

■ 5 medicines selected between 03/08/2022 - 03/08/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

| Medicine summa | List of reports | | | |
|----------------------------------|---|---------------------|--|--|
| Medicine summ | ary | | | |
| The medicine summadverse events. | ary groups reported adverse ev | ents together. Pati | ents may have re | ported multiple |
| Further information | about the medicine summary | | | |
| Information on print | ing search results | | | |
| Sort by: | | | | rsion of this |
| Number of cases - h | nighest first | | report | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
| Cardiac disorders | Cardiac failure | 1 | 1 | 1 |

Case No 747478 – 45 - sex undisclosed

Extracted from DAEN 17/8/22 @ 8.15am

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 747478 | 03/08/2022 | 45 | - | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Cardiac failure |

■ <u>5 medicines selected</u> between 03/08/2022 - 03/08/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Loss of control of legs | 1 | 1 | 1 |

Case No 747503 - 87 Male

Extracted from DAEN 17/8/22 @ 8.28am

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|--|
| 747503 | 03/08/2022 | 87 | M | COMIRNATY COVID-19 vaccine (tozinameran) Suspected COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Not suspected | Haematemesis Hyperhidrosis Ileus Influenza Loss of control of legs Myalgia Nausea Pulmonary embolism Pyrexia Retroperitoneal haemorrhage Small intestinal obstruction Syncope Vomiting |

■ 5 medicines selected between 05/08/2022 - 05/08/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

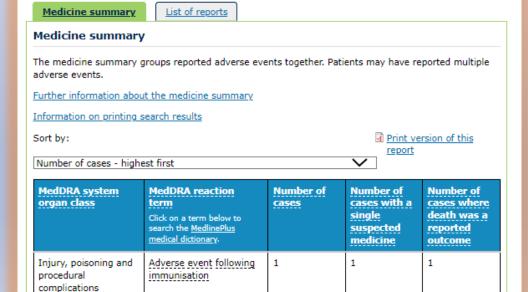
The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results



Case No 747900 – 35 Female

Extracted from DAEN 19/8/22 @ 4.59pm

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 747900 | 05/08/2022 | 35 | F | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Adverse event following immunisation |

■ 5 medicines selected between 11/08/2022 - 11/08/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 4

Number of cases with a single suspected medicine: 4

Number of cases where death was a reported outcome: 4

■ More information on the search results

| Medicine summary | summary List of reports | | | | | | |
|--|--|---------------------|--|--|--|--|--|
| Medicine summary | , | | | | | | |
| adverse events. | groups reported adverse ev | ents together. Pati | ents may have re | ported multiple | | | |
| Further information abou | ut the medicine summary | | | | | | |
| Information on printing s | search results | | | | | | |
| Sort by: | | | Print ve | rsion of this | | | |
| Number of cases - high | est first | | V | | | | |
| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome | | | |
| Injury, poisoning and procedural complications | Adverse event following immunisation | 4 | 4 | 4 | | | |

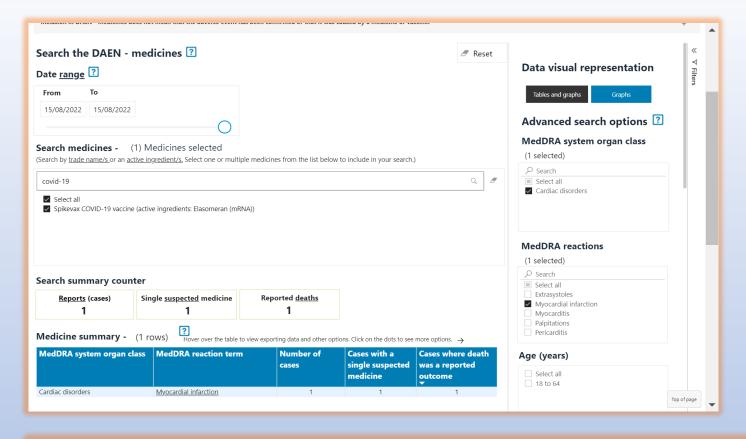
Case No 748626 – 44 Female Extracted from DAEN 27/8/22 @ 3.35pm Extracted from DAEN 27/8/22 @ 3.35pm

Case No 748627 – 57 Female

Case No 748628 – 77 Male Extracted from DAEN 27/8/22 @ 3.35pm

Case No 748629 – 48 Male Extracted from DAEN 27/8/22 @ 3.35pm

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 748626 | 11/08/2022 | 44 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |
| 748627 | 11/08/2022 | 57 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |
| 748628 | 11/08/2022 | 77 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation Cardiac contusion Flank pain Troponin increased |
| 748629 | 11/08/2022 | 48 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |



Case No 748864 – 63 Male

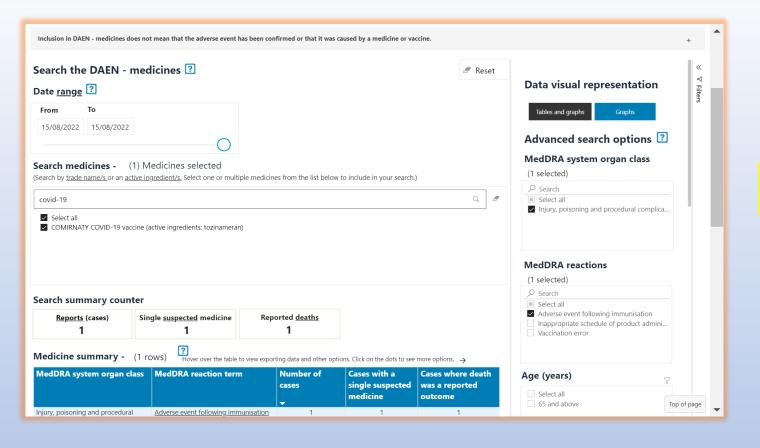
Extracted from DAEN 31/8/22 @ 8.50am

List of reports - (1 rows)

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Hover over the table to view exporting data and other options. Click on the dots to see more options. \rightarrow

| Case number ▼ | Report entry date | Age (years) | Gender | Medicines reported as being taken | MedDRA reaction terms |
|----------------------|-------------------|-------------|--------|---|--|
| 748864 | 15/08/2022 | 63 | Male | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Brain injuryDyspepsiaMyocardial infarctionRenal injuryThrombosis |



Case No 748955 – 66 Male

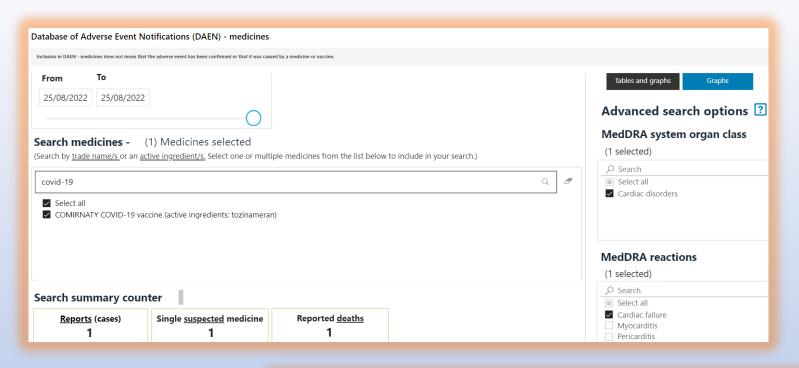
Extracted from DAEN 31/8/22 @ 9.14am

List of reports - (1 rows)

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Hover over the table to view exporting data and other options. Click on the dots to see more options. \rightarrow

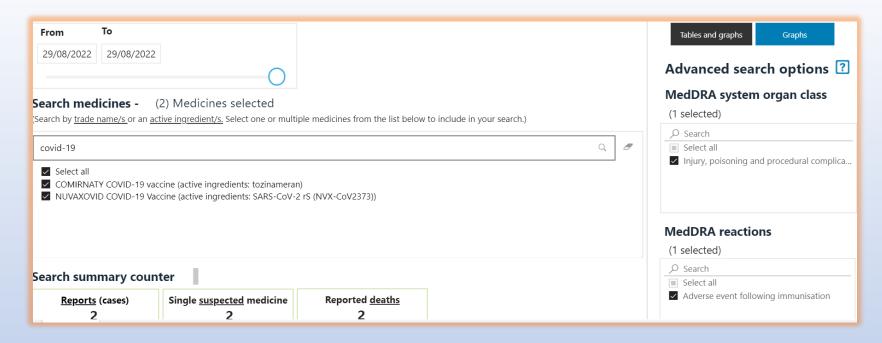
| Case number ▼ | Report entry date | Age (years) | Gender | Medicines reported as being taken | MedDRA reaction terms |
|----------------------|-------------------|-------------|--------|---|--------------------------------------|
| 748955 | 15/08/2022 | 66 | Male | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Adverse event following immunisation |



Case No 750056 – 79 Female

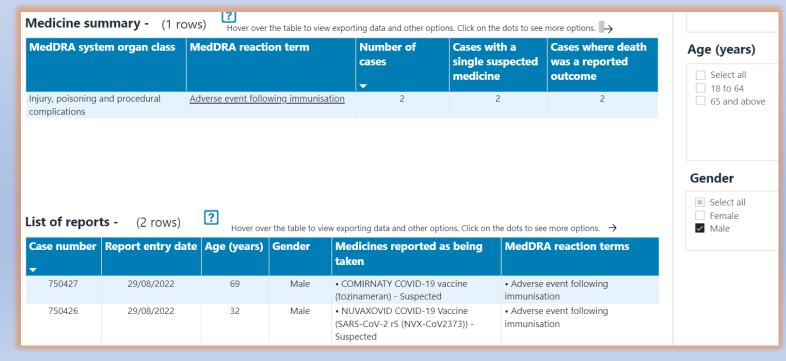
Extracted from DAEN 08/09/22 @ 8.10am

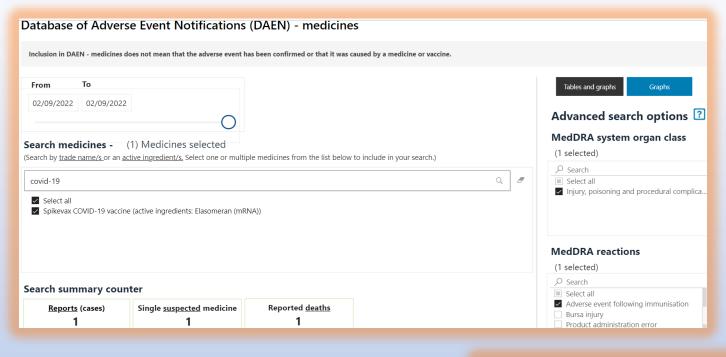
| List of repor | ts - (1 rows) | Hover ove | er the table to vie | w exporting data and other options. Click on t | the dots to see more options. \rightarrow |
|----------------|----------------------|-------------|---------------------|---|---|
| Case number ▼ | Report entry date | Age (years) | Gender | Medicines reported as being taken | MedDRA reaction terms |
| 750056 | 25/08/2022 | 79 | Female | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Not suspected | Anal incontinence Areflexia Aspiration Cardiac failure Confusional state Diarrhoea Hypoxia Pulmonary oedema Pyrexia Respiratory failure Tachycardia Vomiting |



Case No 750427 – 69 Male Extracted from DAEN 12/09/22 @ 10.20am

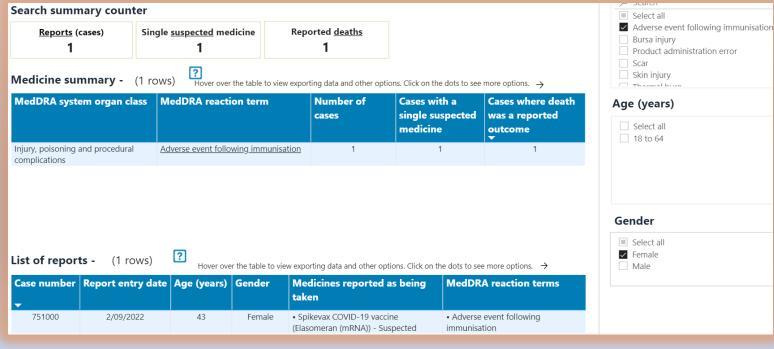
Case No 750426 – 32 Male
Extracted from DAEN 12/09/22 @ 10.20am

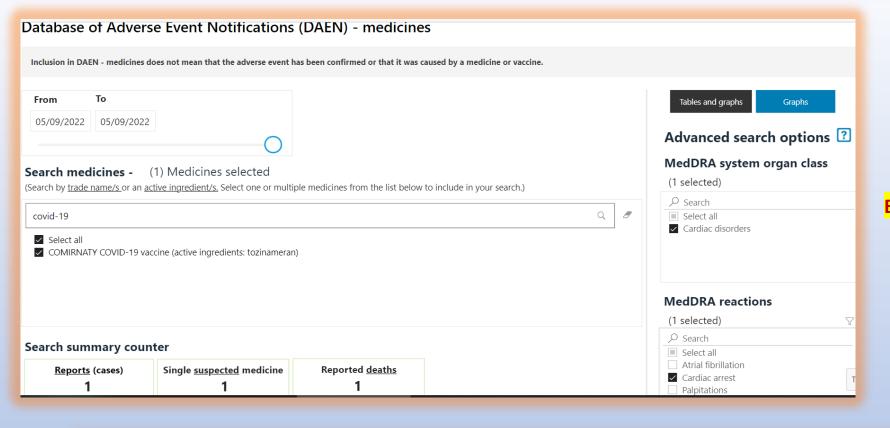




Case No 751000 – 43 Female

Extracted from DAEN 16/09/22 @ 8.13am





Case No 751115 – 69 Male Extracted from DAEN 19/09/22 @ 3.00pm

List of reports - (1 rows)

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Hover over the table to view exporting data and other options. Click on the dots to see more options. →

| Case number ▼ | Report entry date | Age (years) | Gender | Medicines reported as being taken | MedDRA reaction terms |
|----------------|-------------------|-------------|--------|---|--|
| 751115 | 5/09/2022 | 69 | Male | COMIRNATY COVID-19 vaccine (tozinameran) - Suspected | Cardiac arrestConcomitant disease aggravatedSwelling |

- 5 medicines selected between 09/09/2022 09/09/2022.
- 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

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Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | Adenocarcinoma pancreas | 1 | 1 | 1 |

Case No 751718 – 89 Female

Extracted from DAEN 23/09/22 @ 8.40am

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 751718 | 09/09/2022 | 89 | F | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Adenocarcinoma pancreas |

■ 5 medicines selected between 18/09/2022 - 18/09/2022.

Selected medicines

| Trade name | Active ingredients |
|------------------------------|---------------------------------------|
| COMIRNATY COVID-19 vaccine | tozinameran |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single $\underline{\text{suspected}}$ medicine: $\mathbf{1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

Medicine summary

<u>List of reports</u>

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Number of cases - highest first

Print version of this report

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| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|--|--|-----------------|--|--|
| General disorders and administration site conditions | Fatigue | 1 | 1 | 1 |

Case No 752444 – 54 Male

Extracted from DAEN 03/10/22 @ 9.40am

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|---|
| 752444 | 18/09/2022 | 54 | М | COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected | Fatigue Haemophagocytic lymphohistiocytosis Night sweats Pyrexia |

■ 5 medicines selected between 04/10/2022 - 04/10/2022.

Selected medicines

| Trade name | Active ingredients | |
|------------------------------|---------------------------------------|--|
| COMIRNATY COVID-19 vaccine | tozinameran | |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) | |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) | |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) | |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) | |

■ 1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: 1

Number of cases where $\underline{\text{death}}$ was a reported outcome: $\mathbf{1}$

More information on the search results



Case No 753938 – 75 Male

Extracted from DAEN 18/10/22 @ 10.39am

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|---|--|
| 753938 | 04/10/2022 | 75 | М | Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected | Cardiac arrest |

■ 5 medicines selected between 06/10/2022 - 06/10/2022.

Selected medicines

| Trade name | Active ingredients | |
|------------------------------|---------------------------------------|--|
| COMIRNATY COVID-19 vaccine | tozinameran | |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) | |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) | |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) | |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) | |

■ 1 MedDRA Reaction Terms selected.

Extracted from the DAEN On 20/10/22 @ 9am

Search results

The results are shown in two tabs.

https://apps.tga.gov.au/PROD/

Number of reports (cases): 1

DAEN/daen-report.aspx

Number of cases with a single <u>suspected</u> medicine: 1

Number of cases where <u>death</u> was a reported outcome: 1

■ More information on the search results



Case No 754198 – 49 Male

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 754198 | 06/10/2022 | 49 | М | COMIRNATY COVID-19 vaccine (tozinameran) Suspected | Acute myocardial infarction |

■ 5 medicines selected between 11/10/2022 - 11/10/2022.

Selected medicines

| Trade name | Active ingredients | |
|------------------------------|---------------------------------------|--|
| COMIRNATY COVID-19 vaccine | tozinameran | |
| COVID-19 Vaccine (TNS) | COVID-19 Vaccine (Type not specified) | |
| COVID-19 Vaccine AstraZeneca | ChAdOx1-S (Viral vector) | |
| NUVAXOVID COVID-19 Vaccine | SARS-CoV-2 rS (NVX-CoV2373) | |
| Spikevax COVID-19 vaccine | Elasomeran (mRNA) | |

1 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 1

Number of cases with a single suspected medicine: ${f 1}$

Number of cases where death was a reported outcome: 1

■ More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary

Information on printing search results

Sort by:

Print version of this report

Number of cases - highest first

| MedDRA system organ class | MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary. | Number of cases | Number of cases with a single suspected medicine | Number of cases where death was a reported outcome |
|---------------------------------|---|-----------------|--|--|
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |

Case Number – 754639 – Male Age 49

Extracted from DAEN on 25/10/22 @ 4.38pm

| Case number | Report entry date | Age (yrs) | Gender | Medicines reported as being taken | MedDRA reaction terms Click on a term below to search the MedlinePlus medical dictionary. |
|----------------|----------------------|--------------|--------|--|---|
| 754639 | 11/10/2022 | 49 | М | COMIRNATY COVID- 19 vaccine (tozinameran) - Suspected | Abdominal pain Cardiac arrest Coagulopathy Faeces discoloured Gastrointestinal haemorrhage Hypoperfusion Hypovolaemic shock Multiple organ dysfunction syndrome |